Unannounced Inspection Report
18 February 2020

Hillsborough Private Clinic

Type of Service: Independent Hospital – Surgical Services
Address: Cromlyn House, 2 Main Street, Hillsborough BT26 6AE
Tel No: 028 9268 8899

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

Membership of the Inspection Team

Jo Browne	Senior Inspector, Independent Healthcare Team Regulation and Quality Improvement Authority
Dr Gerry Lynch	Senior Medical Advisor Regulation and Quality Improvement Authority
Jean Gilmour	Lead Inspector, Hospital Programmes Team Regulation and Quality Improvement Authority
Carmel McKeegan	Inspector, Independent Healthcare Team Regulation and Quality Improvement Authority
Catherine Glover	Acting Senior Inspector, Medicines Management Team Regulation and Quality Improvement Authority
Gavin Doherty	Inspector, Premises Team Regulation and Quality Improvement Authority
Dr Ian Gillan	RQIA's Medical Physics Expert

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 the Hospital

Hillsborough Private Clinic provides a wide range of services and treatments, including outpatient services across a range of medical specialties; diagnostic tests and investigations; and surgical day case procedures. There are no overnight beds provided in this service.

3.0 Service details

Organisation/Registered Provider: Hillsborough Private Clinic **Responsible Individuals:** Mr Gary McKee Mr James Sharkey	**Registered Manager:** Mrs Dianne Shanks
Person in charge at the time of inspection: Mrs Dianne Shanks	**Date manager registered:** 1 May 2007
Categories of care: Independent Hospital (IH) AH(DS) - Acute Hospital (Day Surgery) PD - Private Doctor PT (L) - Laser PT (E) – Endoscopy	

Laser equipment

Manufacturer: Nidek

Model: YC-1800

Laser Class: 3B

Wave Length: Nd YAG 1064nm

Serial Number: Y1650186

Laser protection advisor (LPA): Anna Bass, Lasermet

Laser protection supervisor (LPS): Mrs Dianne Shanks

Medical support services: Mr James Sharkey

Clinical authorised users: Seven named Consultants Ophthalmologists

Types of treatment provided: Refractive eye surgery

4.0 Inspection summary

We undertook an unannounced inspection to Hillsborough Private Clinic on 18 February 2020 from 09.00 to 17.45.

We employed a multidisciplinary inspection methodology during this inspection. The multi-disciplinary inspection team examined a number of aspects of the hospital from front line care and practices to management and oversight of governance. We met with various staff members, reviewed practice and relevant records and documentation to support the organisational governance and assurance systems.

We would like to thank Mrs Dianne Shanks, Registered Manager and all of the Hillsborough Private Clinic staff for being welcoming, open and transparent, and for providing the inspection team with all information and documents required in a timely manner.

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).

Examples of good practice were evidenced in all four domains. The four domains are outlined in section 1.0 of this report. These related to staffing arrangements; the provision of surgical services; the environment; management of the patients' care pathway; communication; and engagement with patients to enhance their experience.

No immediate concerns were identified in relation to delivery of front line patient care. We noted multiple areas of strength, particularly in relation to organisational management and the delivery of care.

We identified three areas requiring improvement against the regulations in relation to; strengthening of quality assurance arrangements; the development of a venous thrombus embolism (VTE) prevention policy and the development of an antimicrobial stewardship policy.

Three areas for improvement were identified against the standards in relation to formalising the role and function of the Medical Advisory Committee (MAC) review; to strengthen the management of complaints; and to audit clinical records held by medical practitioners outside the hospital.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	3	3

We identified four areas for improvement against the regulations in relation to:

- developing key quality indicators and strengthening the audit programme ;
- development and implementation of a policy for venous thrombus embolism (VTE) prevention; and
- development and implementation of an antimicrobial stewardship policy.

We identified three areas for improvement against the standards in relation to:

- formalising the role and function of the Medical Advisory Committee (MAC);
- the oversight of clinical records held by medical practitioners outside the hospital; and
- the management of complaints.

Details of the Quality Improvement Plan (QIP) were discussed with Mr James Sharkey and Mr Gary McKee, Responsible Individuals and Mrs Dianne Shanks, Registered Manager, during the feedback session on 25 February 2020.

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

At the conclusion of the inspection, Mrs Shanks provided some feedback to the inspection team with respect to the new multidisciplinary inspection methodology. Mrs Shanks stated that the hospital considered the multidisciplinary approach beneficial for the organisation as it produced a detailed assessment of the hospital. We thanked Mrs Shanks for this feedback.

This inspection did not result in enforcement action.

4.2 Enforcement taken following this inspection

Other than those actions detailed in the QIP no further actions were required to be taken.

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; and
- the previous care inspection report.

Our inspection team 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 6.8 of this report.

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

On arrival we met with the Nurse-in-Charge who informed us that Mrs Dianne Shanks, Registered Manager was on leave. The Nurse-in-Charge and the Administrator facilitated the inspection until late morning when Mrs Shanks attended and facilitated the inspection thereafter. Prior to the arrival of Mrs Shanks we found the Nurse-in-Charge and the administrator very capable and able to source all documents requested in a very timely manner.

We met and spoke with the following staff, Mr James Sharkey, Responsible Individual, Mrs Dianne Shanks, Registered Manager, a medical practitioner, nursing and administration staff.

We inspected the reception area, waiting areas, consultation rooms, the main theatre and adjoining recovery area, laser treatment room, store rooms, sluice and patient toilet areas.

As part of the inspection a sample of records was examined during the inspection in relation to each of the areas inspected.

We provided detailed feedback on our inspection findings as described in Section 4.1 of this report.

6.0 The inspection

6.1 Review of areas for improvement from the last care inspection dated 21 February 2019

The previous inspection of the establishment was an announced care inspection undertaken on 21 February 2019. No premises or pharmacy inspections were carried out at this time.

6.2 Review of areas for improvement from the most recent inspections dated 21 February 2019

There were no areas for improvement made as a result of the last care inspection.

6.3 Current inspection findings

6.4 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.

6.4.1 Clinical and organisational governance

We reviewed documentation and discussed the hospital's governance arrangements with a number of staff including Mr James Sharkey, Responsible Individual, Mrs Dianne Shanks, Registered Manager, a medical practitioner and nursing staff.

We reviewed the role and function of Mr Sharkey and Mr McKee, Responsible Individuals in relation to the governance structures of the hospital. Mr Sharkey and Mr McKee are both clinical directors of the hospital and work in the hospital on a weekly basis. We found regular clinical meetings involving all areas of the establishment and additional directors meetings take place.

We established there was a clear organisational structure within the hospital, staff who spoke with us clearly described their roles and responsibilities and were aware of whom to speak to if they had a concern. Staff confirmed that there were good working relationships and that management were responsive to any suggestions or concerns raised. Mrs Shanks is the nominated individual with overall responsibility for the day to day management of the hospital.

We found that policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a three yearly basis. Staff who spoke with us were aware of the policies and how to access them.

6.4.2 Medical governance and the Medical Advisory Committee (MAC)

On discussion it was evident that the clinical and directors meeting was fulfilling the function of a Medical Advisory Committee (MAC) as outlined in Standard 30 of the Minimum Care Standards for Independent Healthcare Establishments (July 2014). We were unable to evidence established terms of reference or standard agenda for the clinical and director meetings. We advised that the clinical/director meetings should be formalised clearly outline the role and function the MAC and ensure terms of reference in accordance with Standard 30 of the Minimum Care Standards for Independent Healthcare Establishments (July 2014) are provided. An area for improvement against the standards has been made in this regard.

We discussed governance in relation to medical practitioners who consult with patients as outpatients and how oversight of this can be captured under the governance structures of the hospital. We advised that, to assure themselves of good medical practice, the hospital should develop a system to randomly select and audit/peer review the medical records of outpatients, including records not stored on site, by someone with the knowledge and skill to identify if there were any concerns. An area for improvement was made against the standards in this regard.

6.4.3 Regulation 26 unannounced quality monitoring visits

In accordance with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, where the entity operating a hospital is a corporate body or partnership or where an individual owner is not in day-to-day management of the hospital, unannounced quality monitoring visits must be undertaken and documented every six months.

Following discussion with Mr Sharkey and Mr McKee we determined that whilst they both visit the establishment on a weekly basis neither are in day-to-day management of the hospital. We advised that an unannounced monitoring visit to the premises should be undertaken at least every six months in accordance with legislation. Reports of the unannounced monitoring visits should be retained and available for inspection and shared with staff. Mr Sharkey and Mr McKee agreed that six monthly unannounced quality monitoring visits would commence and this process will further strengthen the governance arrangements.

6.4.4 Complaints management

We confirmed that the hospital had a complaints policy in place and this was made available to patients/and or their representatives. We established any complaints received were raised through the governance systems of the hospital and were investigated and responded to. We confirmed complaints records included details of all communications with complainants; the result of any investigation; the outcome; and any action taken to address the concerns.

We found that when investigating a complaint about an individual clinician, the hospital requests the clinician involved to respond directly to the complainant. We advised the hospital should have full ownership of the complaint management process in order to ensure there is a robust and independent investigation into the complaint. The hospital should request a response to the issues from the medical practitioner and the hospital should use this information to formulate their response to the complainant. The investigating officer should source an objective independent view of the relevant medical notes and/or the matters subject to the complaint. An area for improvement was made against the standards in this regard.

We suggested that the complaints management process should incorporate a timeframe within the final letter issued to the complainant. This should state that if a response is not received within the specified timeframe the hospital will assume the complainant is satisfied with the outcome and the complaint will be closed. This process will enable the hospital to evidence completion of the complaints management process.

We were advised that complaints are audited to identify patterns and trends and that any learning outcomes would be shared with staff in order to improve care and service delivery.

Staff who spoke with us demonstrated a good awareness of the processes for the management of complaints and complaints awareness training is provided on an annual basis.

6.4.5 Notifiable events/incidents

We reviewed the arrangements in respect of the management of notifiable events/incident and the notifications submitted to us since the previous inspection. We confirmed that a system was in place to ensure that notifiable events/incidents were investigated and reported to RQIA; and other relevant bodies as appropriate within a timely manner.

6.4.6 Practising privileges

We reviewed the arrangements relating to practising privileges for medical practitioners working within the hospital. A practicing privileges policy and procedure was in place which outlines the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

Mrs Shanks outlined the process for granting practising privileges and confirmed medical practitioners meet with her prior to practising privileges being granted. There are systems in place to review practising privileges agreements every two years.

All medical practitioners working within the hospital must have a designated Responsible Officer (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 established that all medical practitioners working within the hospital have a designated external RO due to their prescribed connection with another health care organisation. We discussed with Mr Sharkey how concerns regarding a doctor's practice are shared with the MAC and the wider HSC. We found that good internal arrangements were in place and the hospital is linked in to the regional RO network.

We found there were good oversight arrangements relating to practising privileges. We reviewed three medical practitioner's personnel files and found that there was a written agreement between each medical practitioner and the hospital setting out the terms and conditions of practising privileges; which has been signed by both parties. All relevant documentation was present in relation to professional indemnity, insurance and medical appraisals for these medical practitioners.

We advised that going forward the hospital should request the full appraisal document for each medical practitioner rather than the sign off sheet. The appraisal document should be reviewed and scrutinised by the MAC before granting or renewing practising privileges and record of this review retained. This will provide an added level of assurance for the MAC and can aid in the determination of the agreed scope of practice for each individual medical practitioner while working in Hillsborough Private Clinic.

6.4.7 Risk registers

We were advised that Hillsborough Private Clinic maintains a corporate risk register. Review of this register evidenced that it included risks in relation to all areas of the hospital that have the potential to impact on the delivery of services. We confirmed that the risk register included actions to mitigate against identified risks and that it is routinely reviewed through the hospital governance structures.

6.4.8 Quality assurance

Mrs Shanks confirmed to us that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to patients at appropriate intervals. These included audits in relation to hand hygiene, the environment and surgical site infection. Staff told us if required, an action plan was developed and embedded into practice to address any shortfalls identified during the audit process.

We identified some audits were undertaken routinely regardless of the previous findings, for example, an audit was undertaken monthly and confirmed a consistently high compliance rate. We suggested reducing the frequency of this audit and identifying other areas to be audited. The frequency of audit and re-audit should be determined by the outcome and the information gathered should be used to drive improvements and assure best practice across the hospital.

We advised that the audit programme should be revised and strengthened, under the direction of the MAC, to be more meaningful in identifying and addressing issues and providing assurance of safe and effective care.

We also discussed the value of developing a core set of key performance indicators to include areas such as complaints, incident, transfers out and surgical infection rates. These key quality indicators will enable oversight and assurance of good and best practice throughout the hospital. Where issues are identified through audit an action plan should be developed and embedded into practice to address any shortfalls identified. The key quality indicators and outcomes of audits and actions required should be shared with the MAC and the learning shared with relevant staff members. An area for improvement against the regulations has been made in this regard.

6.4.9 Management of operations

We discussed the operational management arrangements of the hospital with Mrs Shanks who, as the registered manager, has overall responsibility for the day to day management of the hospital. We confirmed there was a system 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 found that the hospital has arrangements in place to monitor the competency and performance of all staff and report to the relevant professional regulatory bodies in accordance with best practice guidance. We identified there are also robust systems in place to check the registration status of the health care professionals with their appropriate professional bodies on an annual basis.

We reviewed and confirmed that the statement of purpose and patient's guide are kept under review, revised and updated when necessary and these are available on request.

We observed that the RQIA certificate of registration was up to date and displayed appropriately. Review of insurance documentation confirmed that current insurance policies were in place.

The hospital has a Whistleblowing policy and procedure in place to enable staff to report concerns they may have regarding poor practice. Staff who spoke with us confirmed that they were aware of the policy and who to contact if they had any concerns.

Areas of good practice: Is the service well led?

There were examples of good practice found in relation to organisational governance, management of incidents and quality assurance.

Areas for improvement: Is the service well led?

Areas for improvement were made in relation to formalising the role and function of the MAC; implement a system of audit audit/peer review of the medical records of outpatients, including records not stored on site, by someone with the knowledge and skill to identify if there were any concerns; complaints management; the development of core key quality indicators and revision of the audit programme to strengthen quality assurance.

	Regulations	Standards
Areas for improvement	1	3

6.5 Is care safe?

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

6.5.1 Staffing

We reviewed the staffing arrangements within the hospital. Discussion with Mrs Shanks and staff demonstrated that there was sufficient staff in various roles to fulfil the needs of the hospital and patients.

We were advised that two new staff members have been recruited since the previous inspection. We evidenced that both new staff members had undertaken a formal induction programme. We found that a range of induction templates were available for specific roles within the hospital and found these to be of a satisfactory standard.

Procedures were in place for appraising staff performance and staff told us that appraisals had taken place. Review of records evidenced that appraisals had been completed on an annual basis.

We found that there were systems in place for recording and monitoring all aspects of staff ongoing professional development, including specialist qualifications and training. Staff reported they felt supported and involved in discussions about their personal development.

We identified that professional supervision was not routinely undertaken in the hospital. We advised staff should have supervision corresponding with their role and responsibilities and a written record or evidence of professional supervision having taken place should be retained for inspection.

Discussion with staff and review of a sample of training records confirmed that the hospital provides annual mandatory training appropriate to staff roles and responsibilities. Examples of mandatory training delivered included; fire safety awareness; infection prevention and control; basic and intermediate life support; safeguarding; and manual handling. We advised safeguarding training should be extended to also include administration staff.

Arrangements were in place to ensure that all health and social care professionals are aware that they are accountable for their individual practice and adherence to professional codes of conduct. Discussion with Mrs Shanks confirmed that a robust system was in place to review the professional indemnity status of all staff that require individual indemnity cover.

We found a process was in place to review the registration details of all health and social care (HSC) professionals. We reviewed a sample of personnel files of HSC medical practitioners and evidenced the following was in place:

- confirmation of identity;
- current registration with the General Medical Council (GMC);
- appropriate professional indemnity insurance;
- appropriate qualifications, skills and experience;
- ongoing professional development and continuing medical education that meet the requirements of the Royal Colleges and GMC; and
- ongoing annual appraisal by a trained medical appraiser.

As previously discussed we confirmed each HSC medical practitioner has an appointed RO. We were told there are no Private Doctors currently working in the hospital. Review of personnel files confirmed that medical practitioners had appropriate professional indemnity insurance in place.

Staff told us there are good working relationships across the hospital. They all spoke positively regarding the establishment, felt valued as members of the team and confirmed they were supported by management.

6.5.2 Recruitment and selection

We reviewed how recruitment and selection of staff is undertaken by the hospital. We found there was a recruitment and selection policy and procedure available which was comprehensive and reflected best practice guidance.

As previously stated, we were told that two new staff had been recruited since the previous inspection. We reviewed both staff members' personnel files and confirmed all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 had been sought and retained for inspection.

6.5.3 Surgical services

We reviewed the provision of surgical services within the hospital. We found that the hospital has a wide range of comprehensive policies and procedures in place to ensure that safe and effective care is provided to patients, which are in accordance with best practice guidelines and national standards.

Within the hospital, there is a defined staff structure for surgical services, which clearly outlines areas of accountability and individual roles and responsibilities. The scheduling of patients for surgical procedures is co-ordinated by Mrs Shanks or other delegated senior nurse, the Consultant and administration staff. We determined the theatre list takes into account the individual requirements of the patient, the type of procedure to be performed, availability of equipment, staffing levels required and associated risks. Mrs Shanks confirmed that all procedures were undertaken as day surgery cases using local anaesthesia, where necessary. No procedures were performed under general anaesthesia.

Staff who spoke with us confirmed that the Consultant performing the surgical procedure meets with the patient, prior to commencing the procedure, to discuss the surgery and anaesthesia used, obtain informed consent and agree options for post-operative pain relief.

We confirmed there is an identified member of nursing staff, with theatre experience, in charge of the operating theatre. Discussion with staff confirmed that patients are observed during and immediately following surgery. Discharge criteria is in place to check the patient's condition and appropriateness to transfer to the waiting area or home following the procedure. We were advised that the Consultant who performs the procedure confirms when the patient is suitable for discharge from the hospital.

We reviewed the surgical register of operations, which is maintained for all surgical procedures undertaken in the hospital and found that it contained all of the information required by legislation. Staff informed us that the surgical checklist used in the hospital was adapted from the World Health Organisation (WHO) checklist.

6.5.4 Laser safety

During April 2019 Mrs Shanks had informed RQIA the hospital had purchased a new laser machine and advised refractive eye surgery would be undertaken by named Consultant Ophthalmologists.

We reviewed the arrangements in respect of the use of the laser machine. We found a laser safety file was in place that contained all of the relevant information in relation to the laser equipment.

We reviewed the procedures in place for the safe use of laser equipment within Hillsborough Private Clinic. We found there was written confirmation of the appointment and duties of a certified Laser Protection Advisor (LPA). We were informed the LPA appointed in April 2019 had retired and a new LPA had subsequently been appointed.

We reviewed the service level agreement between Hillsborough Private Clinic and their newly appointed LPA which expires on 14 November 2020 and found this to be a satisfactory arrangement.

We established that named Consultants in accordance with Treatment Protocols, carry out Capsulotomy and Iridectomy refractive eye procedures using the laser machine. We found a system was in place to review the Treatment Protocols on an annual basis. Review of the Treatment Protocols identified the following;

- pages 19 and 21 of the Treatment Protocols provide contact details for the clinic's previous LPA, this should be replaced with the contact details for their current LPA; and
- although the cover sheet for the Treatment Protocol states that the document has been checked by a named Registered Medical Practitioner (RMP), the document control process does not clearly show that the protocol is written and approved by the RMP.

Discussion with Mrs Shanks, as the Laser Protection Supervisor (LPS) confirmed that these areas were in the process of being addressed.

We found Local Rules developed by the current LPA they contained relevant information pertaining to the laser equipment being used and had been signed by the seven named Consultants and other staff involved in laser procedures. We noted the Local Rules needed updated to state that in the event of a suspected eye injury, an ophthalmic examination should be carried out at the Royal Victoria Hospital rather than the Lagan Valley Hospital as currently stated. We were assured the LPS was addressing this matter.

We found the current LPA completed a risk assessment on 19 November 2019 in relation to the use of the laser, we noted an action point had been made to ensure that the available Treatment Protocols also refer to Iridectomy in addition to Capsulotomy. This area was discussed with Mrs Shanks who confirmed this point has been addressed. Mrs Shanks confirmed the updated Treatment Protocols will be shared with and signed by all authorised operators and retained in the laser safety file.

We reviewed the Laser Safety Policy and identified that this policy outlines 'The Health and Safety at Work Act 1974' and the role of the Care Quality Commission, this should be amended to refer to Northern Ireland legislation and the role of RQIA. Mrs Shanks acknowledged this was an oversight when fresh documents had been provided by the current LPA and confirmed the Laser Safety Policy will be corrected accordingly.

Staff training records were available for all seven authorised operators in relation to laser safety, core of knowledge and applications training for the specific laser system. We observed a robust process was in place to monitor training and ensure compliance in this area.

We found safe and effective arrangements in place for the use of laser equipment including controlled access to the environment; displaying of laser safety warning signs; controlled access to the laser operating key; clear identification of the authorised LPS and arrangements for deputisation; maintenance of equipment; and servicing. We established that protective eyewear was available as outlined in the Local Rules.

The Laser Incident Grab Sheet displayed on the wall of the laser treatment room refers to the previous LPA. We were informed that the Incident Grab Sheet would be updated to provide the current LPA's contact details.

We reviewed the laser surgical register which is completed every time the equipment is operated and evidenced that it included the following information:

- the name of the person treated;
- the date;
- the operator;
- the treatment given;
- the precise exposure; and
- any accident or adverse incident.

At the end of each treatment, a record was made in the laser register of the frequency and single pulse energy settings displayed on the laser control panel. We were satisfied the total energy delivered during each treatment session had been consistently recorded.

6.5.5 Safeguarding

We reviewed the arrangements in place for safeguarding and found that policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust (HSCT) should a safeguarding issue arise were included.

It was confirmed that copies of the regional policy entitled 'Co-operating to Safeguard Children and Young People in Northern Ireland' (August 2017) and the regional guidance document entitled 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) were both available for staff reference.

We discussed safeguarding with staff and found good general awareness of the types and indicators of abuse, along with the actions to be taken in the event of a safeguarding issue being identified. Staff were able to identify the nominated safeguarding lead for the hospital.

Review of records demonstrated that front line staff in the hospital had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. We advised that safeguarding children and adults training should be extended to include administration staff.

We were informed the hospital provides outpatient services for children. Mrs Shanks and hospital staff advised that a parent/guardian is always present during the child's outpatient consultation and in the waiting area.

6.5.6 Resuscitation and management of medical emergencies

We reviewed the arrangements for the management of a medical emergency and resuscitation of patients and visitors to the hospital. We found the hospital has a policy and procedure for dealing with medical emergencies and cardio pulmonary resuscitation (CPR) that was in accordance with the Resuscitation Council (UK) guidelines.

Discussion with staff demonstrated that they had a good understanding of the actions to be taken in the event of a medical emergency and the location of medical emergency medicines and equipment. Staff told us periodic resuscitation drills are undertaken.

We reviewed the emergency trolley and evidenced that emergency medicines and emergency equipment was available. We noted that a system was in place to ensure that emergency medicines and equipment do not exceed their expiry date.

A review of training records and discussion with staff confirmed that staff had undertaken basic life support training and updates. All permanent nursing staff had received intermediate life support training and updates. We were advised that staff involved in the provision of paediatric care had also received paediatric life support training.

6.5.7 Infection prevention and control (IPC) and decontamination procedures

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

We found there were clear lines of accountability for infection prevention and control and the hospital has a designated IPC Link Nurse. The IPC Link Nurse told us that she engages with the regional IPC group and also has the support of an Independent IPC advisor.

We found arrangements were in place to ensure the decontamination of equipment and reusable medical devices in line with manufacturer's instructions and current best practice. Endoscopes and reusable medical instruments are decontaminated within a Health and Social Care Central Sterile Services Department (CSSD). Staff who spoke with us advised that single use equipment is used where possible.

We spoke with nursing staff who demonstrated a good understanding of IPC measures in line with best practice and told us they have access to the Northern Ireland Regional Infection Control Manual online for additional guidance. Discussion with staff demonstrated they were knowledgeable on the management of a patient with an infection risk. Staff also effectively described how they would undertake venepuncture in line with aseptic non-touch technique (ANTT) practices and demonstrated good knowledge of the principles of the ANTT framework. We identified that ANTT training is not included within IPC mandatory training or induction training. Mrs Shanks and the IPC Link Nurse confirmed ANTT training would be included in mandatory IPC training and induction training for all clinical staff moving forward.

We found IPC policies and procedures are regularly reviewed and updated to reflect the most recent best practice guidance. We noted clear guidance is provided on making referrals for advice and support to the independent IPC advisor and/or microbiologists required.

We found an IPC programme of audits was in place with evidence of information sharing to promote adherence to IPC standards. We evidenced that there were cleaning schedules in place for all areas which were signed on completion and we observed that a colour coded cleaning system was in use in accordance with best practice guidance.

Overall we found 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 Mrs Shanks who took immediate action. During feedback on 25 February 2020 the hospital demonstrated that the equipment cleaning schedule had been updated and a fresh auditing process commenced to ensure future compliance 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.

6.5.8 Medicines management

We reviewed the arrangements in place for the management of medicines with in the hospital to ensure that medicines are safe, secure and effectively managed in compliance with legislative requirements, professional standards and guidelines. We found the arrangements in place to be largely satisfactory.

We found that policy and procedure documents for the management of medicines were in place, up to date and available for staff reference. We noted that systems were in place to ensure that these documents were kept under review. The nursing staff who spoke with us demonstrated a good knowledge of the medicines management policy and procedures.

We evidenced that Standard Operating Procedures (SOPs) were in place that cover all aspects of the management of controlled drugs in line with DoH guidelines for the management of controlled drugs in primary care. Mrs Shanks is the Accountable Officer (AO) who has responsibility for securing the safe management and use of controlled drugs in accordance with the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

We found that there were robust arrangements in place for the management of medicine related incidents. We confirmed three medicine related incidents had been reported since the last medicines management inspection on 17 August 2017 and these had been managed appropriately.

We reviewed a sample of medicine records which had been clearly and appropriately completed by the Consultants, Anaesthetists and Nurses.

We found medicines required for resuscitation or other medical emergency are clearly defined and are checked daily when the hospital is operational.

There were arrangements in place to audit all aspects of the medicines management. Controlled drugs are audited regularly and audits also include an examination of the medicine records and medicines given to patients on discharge.

We established robust systems were in place to manage the ordering of prescribed medicines to ensure adequate supplies were available and to prevent wastage. The stock requisition forms are signed by a Registered Nurse. Mrs Shanks had sought clarification from the Medicines Regulatory Group and it was confirmed on 5 March 2020 that this practice is appropriate for the clinic.

We identified that an antimicrobial stewardship policy had not yet been implemented. We were informed that antibiotics are only prescribed following podiatry procedures and Senior Management had already identified that an antimicrobial policy should be implemented. We were advised that the hospital is in the process of developing an antimicrobial stewardship policy.

We advised that the hospital strengthen their anti-microbial/antibiotic stewardship as follows:

- ensure that an anti-microbial/antibiotic stewardship policy is developed in keeping with NICE guideline [NG15];
- ensure the MAC and relevant clinicians/clinical groups actively contribute to the development of the policy;
- ensure the policy clearly describes the prophylactic medications that may be prescribed by clinicians practising in the hospital; and
- ensure that a rolling audit programme is developed to provide assurance that the policy is being adhered to.

An area for improvement has been made against the regulations in this regard.

The NICE guideline [NG89] Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism advises that all surgical patients are assessed for the risk of venous thromboembolism (VTE) and bleeding on admission. We reviewed the arrangements for the management VTE and found that the hospital needs to develop, implement and assure an appropriate policy for the assessment and prevention of VTE in line with the NICE guideline.

We were advised by senior management that VTE assessment is only undertaken for podiatry procedures and the current approach permits clinicians to prescribe individually as opposed to adhering to prescribing guidance issued by the hospital. .

The hospital must undertake the following matters with respect to the management of VTE:

- review the current VTE management policy and ensure that it is in keeping with NICE guideline [NG89];
- ensure that the MAC and other relevant clinicians approve and contribute to the updated VTE policy;
- ensure the VTE risk assessments are undertaken and documented in respect of all patients admitted for surgical procedures; and
- develop a rolling audit programme to provide assurance that the VTE policy is being adhered to.

An area for improvement has been made against the regulations in this regard.

6.5.9 Environment

We found that the overall environment including the entrance, reception, theatre, treatment rooms and consultation rooms were of a high standard of maintenance and décor.

We reviewed documentation in relation to the maintenance of the premises including mechanical and electrical services. Discussion with Mrs Shanks demonstrated that suitable arrangements are in place for maintaining the environment in accordance with current legislation and best practice guidance. The following documents were reviewed:

- 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;
- Lifting Operations and Lifting Equipment Regulations (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; and
- service records and validation checks for the premises' specialist ventilation systems.

We found the current Legionella Risk Assessment was undertaken on 30 July 2018 and all required remedial works were completed on 31 August 2018. Suitable temperature monitoring of the premises' hot and cold water systems was in place with records being maintained as recommended. We established that a full chemical treatment of the premises' hot and cold water systems was undertaken on 11 September 2019. Regular bacteriological sampling of the hot and cold water systems most recently undertaken on 15 October 2019 confirmed that legionella and pseudomonas bacteria were not detected.

We noted the Fire Risk Assessment had been undertaken by a suitably accredited fire risk assessor on 3 February 2020. 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 29 January 2019. We were told that new staff members had been instructed on the action to take in the event of a fire occurring and that a fire drill will be completed imminently during upcoming fire safety training. Staff demonstrated that they were aware of the action to be taken in the event of a fire.

We confirmed the premises' specialised ventilation systems are serviced in accordance with current best practice guidance and suitable validation is undertaken in accordance with the current health technical memoranda. Records and validation reports were available and reviewed at the time of the inspection.

Areas of good practice: Is Care Safe?

Areas of good practice were found in relation to staffing; recruitment and selection; surgical services; laser safety; arrangements for the management of a medical emergency; infection prevention and control; and the environment.

Areas for improvement: Is Care Safe?

Areas for improvement were identified in relation to the development and implementation of an antimicrobial stewardship policy and an appropriate policy for venous thrombus embolism (VTE) prevention.

	Regulations	Standards
Areas for improvement	**2**	**0**

6.6 Is care effective?

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

6.6.1 Care pathway

We tracked the patient care pathway through the hospital from the time of referral through to the point of discharge. Many areas of good practice were identified with respect to the services and care delivered. We evidenced that patients are provided with comprehensive information prior to their surgical procedure which outlines any pre-operative and post-operative requirements.

We reviewed three patient's care records and found that the care records contained comprehensive information relating to pre and post-operative care which clearly outlined the patient pathway and included the following:

- patient personal information;
- pre-operative care plans;
- pre-operative checks;
- signed consent forms;
- surgical safety checklist;
- procedure notes;
- medical notes;
- post-operative checks; and
- discharge plan.

As previously reported under Section 6.5.4 staff who spoke with us confirmed that patients attending for a surgical procedure receive written information regarding their treatment and meet with their Consultant prior to going to theatre to discuss the nature of the surgery, the risks, complications and expected outcomes before signing the consent form. The consent forms reviewed by us were found to be in line with best practice guidance and signed by the Consultant Surgeon and the patient.

6.6.2 Records management

We reviewed the management of records within the hospital and confirmed that the hospital is registered with the Information Commissioner's Office (ICO). Through discussion with staff it we established that the hospital is aware of and is complying with the General Data Protection Regulations 2018 (GDPR).

Staff demonstrated they had a good knowledge of effective records management procedures. The hospital 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.

The establishment also has a policy and procedure in place for clinical record keeping in relation to patient care and treatment which complies with (GMC) guidance, Good Medical Practice and other professional bodies' guidance.

The management of records within the hospital was found to be in line with legislation and best practice.

Patient records were held in secure cabinets and computerised records were accessed by only those with password permission. Records required by legislation were retained and made available to us.

We were told that a number of medical practitioners do not store their patient records in the hospital; instead they are responsible for adhering to best practice guidance in regards to the records generated by them. We were informed that all medical practitioners with practising privileges sign a data controller agreement regarding the records they hold to confirm they are registered with the ICO and that they will manage these records in accordance with GDPR.

As discussed in Section 6.4.2 the hospital was advised to implement a system to randomly select and audit/peer review the medical records of outpatients, including those not stored in the clinic, by someone with the knowledge and skill to identify if there were any concerns. As previously stated outcomes of audits and actions required should be shared with the MAC and learning shared with the relevant medical practitioners.

6.6.3 Discharge planning

We reviewed the discharge arrangements and established that discharge criterion is in place and we were advised the Consultant who performs the procedure confirms the patient's suitability for discharge from the hospital.

We found robust systems were in place to ensure that agreed discharge arrangements are recorded and co-ordinated with all professionals that are involved in the patient's ongoing care and treatment. A clinical discharge summary is completed prior to the patient leaving the hospital and a discharge letter is provided to the patient's General Practitioner (GP) to outline the care and treatment provided within the hospital.

Areas of good practice: Is care effective?

There were examples of good practice found in relation to the patient care pathway, records management and discharge planning.

Areas for improvement: Is care effective?

No areas for improvement were identified during the inspection in relation to effective care

	Regulations	Standards
Areas for improvement	0	0

6.7 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.

6.7.1 Person centred care

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

We were unable to speak with patients during our inspection however we observed positive interactions between staff and patients during the latter part of our inspection. We observed staff treating patients with compassion, dignity and respect, introducing themselves and explaining procedures to patients in a kind and caring manner. Following the inspection we also reviewed the returned patient questionnaires which demonstrated a high level of satisfaction with the service delivery, care and treatment received. This area is further discussed in Section 6.8. During the consultation and treatment processes we observed that patients' modesty and dignity was respected at all times.

6.7.2 Breaking bad news

We confirmed that the hospital has a Breaking Bad News Policy for delivering bad news to patients and/or their representatives which is accordance with the Breaking Bad News Regional Guidelines 2003.

We spoke with staff who confirmed that bad news is delivered to patients and/or their representatives by professionals who have experience in communication skills and act in accordance with the hospital's policy.

Where bad news is shared with others, staff confirmed that consent must be obtained from the patient and this is then documented in the patient's care records. Following a patient receiving bad news, future treatment options are discussed fully with the patient and documented within their individual care records. Staff provide support to the patient and/or their representative to help them process the information shared. We were advised that information is shared with the patient's GP and/or other healthcare professionals involved in their ongoing treatment and care.

6.7.3 Patient engagement

We examined the methods used by the hospital to obtain the views of patients and/or their representatives and found this to be an integral part of the services delivered. Patients 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 which is made available through the hospital's website. We reviewed the most recent annual report and noted that patients were highly satisfied with the care and treatment provided.

Mrs Shanks informed us that comments received from patients and/or their representatives are reviewed by the Responsible Individuals and are used to improve the quality of services delivered. Where applicable, an action plan is developed and implemented to address any issues identified.

Areas of good practice: Is care compassionate?

We found examples of good practice in relation to ensuring the core values of privacy and dignity were upheld; arrangements for delivering bad news in a compassionate and supportive manner; and considering feedback from patients to improve the quality of services provided.

Areas for improvement: Is care compassionate?

No areas for improvement were identified during the inspection in relation to compassionate care.

	Regulations	Standards
Areas for improvement	0	0

6.8 Patient and staff views

During our inspection the establishment distributed patient questionnaires on our behalf. We received three completed patient questionnaires. Patients responded that they were very satisfied that the hospital was providing safe, effective, compassionate and well led care. One respondent provided an additional comment expressing a high level of satisfaction with the service delivery and treatment they had received.

RQIA invited staff to complete an electronic questionnaire during the inspection. We received six completed staff patient questionnaires following the inspection. Staff responded that they felt the hospital was providing safe, effective, and compassionate care and the service was well led. Four respondents provided additional comments which demonstrated a high level of satisfaction in relation to leadership shown by senior management to staff who feel supported and appreciated.

7.0 Quality Improvement Plan (QIP)

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Mr James Sharkey and Mr Gary McKee, Responsible Individuals and Mrs Dianne Shanks, Registered 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 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 because of this inspection are set in the context of the current registration of the independent hospital. 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.

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 and The Minimum Care Standards for Independent Healthcare Establishments (2014)

Clinical Governance	
Area for improvement 1 **Ref**: Standard 30.1 **Stated:** First time **To be completed by:** 25 May 2020	The Registered Persons shall ensure the role of the Medical Advisory Committee (MAC) is formalised with terms of reference provided in accordance with Standard 30. The MAC should meet quarterly as a minimum with formal minutes kept and a record of meetings maintained. Ref: 6.4.2
	Response by registered person detailing the actions taken: Terms of Reference have been agreed in accordance with Standard 30 and a copy of this is enclosed. The MAC have been meeting quarterly and a record of these minutes maintained.
Medical Governance	
Area for improvement 2 **Ref**: Standard 9.3 **Stated:** First time **To be completed by:** 25 May 2020	The Registered Persons shall implement a system of audit/peer review of outpatient's medical records, including those records not stored on site, by someone with the knowledge and skill to identify if there were any concern. A record of the findings, outcome and learning identified should be retained Ref: 6.4.2
	Response by registered person detailing the actions taken: A template has been agreed for audit of outpatients medical records and is enclosed. Auditing has commenced, a record of findings maintained, and learning from this addressed. Records which are to be stored off site, will be audited prior to being taken off site. The auditor will be directed by the MD to use the template adapted from MDU Good Record Keeping – Staying Patient Focused Document. Each discipline will be asked to provide a list of approved abbreviations.
Complaints management	
Area for improvement 3 **Ref:** Standard 7 **Stated:** First time **To be completed by:** 25 March 2020	The Registered Persons shall ensure that complaint management is revised to ensure the hospital retains full ownership of all complaints received. Ref: 6.4.4
	Response by registered person detailing the actions taken: The complaints policy has been amended to include full ownership of all complaints. Comments from RQIA were acknowledged and actioned with immediate effect.

Quality Assurance	
Area for improvement 4 **Ref**: Regulation 17.1 **Stated:** First time **To be completed by:** 25 May 2020	The Registered Persons shall address the following matters with respect to key quality indicators and the audit programme: • an audit programme agreed by the MAC should be implemented to drive improvements and assure best practice across the hospital. • develop a set of key quality indicators that are evidenced by the audit programme and shared with the MAC and record the evidence of action taken to address any shortfalls; • when issues are identified an action plan should be developed and embedded into practice to address any shortfalls identified. Ref: 6.4.8
	Response by registered person detailing the actions taken: The MAC have identified and commenced an audit programme which will be used to improve patient care. Key quality indicators are in place and discussed at the MAC. An action plan will be developed by the MAC to address shortfalls, whether that be medical or nursing care and followed up at monthly meetings with a report available to the quarterly MAC meeting.
Policy and Best Practice Guidance	
Area for improvement 5 **Ref:** Regulation 15 (1) (b) **Stated:** First time **To be completed by:** 25 May 2020	The Registered Person shall address the following matters with respect to antimicrobial/antibiotic stewardship: • ensure that an anti-microbial/antibiotic stewardship policy is developed in keeping with NICE guideline [NG15]; • ensure the MAC and relevant clinicians/clinical groups actively contribute to the development of the policy; • ensure the policy clearly describes the prophylactic medications that may be prescribed by clinicians practising in the hospital; and • ensure that a rolling audit programme is developed to provide assurance that the policy is being adhered to. Ref: 6.5.9
	Response by registered person detailing the actions taken: An anti-microbial/antibiotic stewardship policy has been drafted - awaiting infection control authorisation.(Draft enclosed) . This includes all of the above.
Area for improvement 6 **Ref**: Regulation 15 (1) (b) **Stated:** First time	The Registered Persons shall address the following matters with respect to the management of venous thromboembolism (VTE): • review the current VTE management policy and ensure that it is in keeping with NICE guideline [NG89]; • ensure that the MAC and other relevant clinicians contribute to and

To be completed by: 25 May 2020	approves the hospital's updated VTE policy; • ensure that VTE risk assessments are undertaken and documented in respect of all patients admitted for surgical procedures; and • develop a rolling audit programme to provide assurance that the VTE policy is being adhered to. Ref: 6.5.9
	Response by registered person detailing the actions taken: The VTE Policy has been amended and is in draft format (enclosed) awaiting MAC approval. VTE risk assessments are undertaken for surgical procedures and are audited as part of the notes audit. A comprehensive audit is being developed to ensure adherence to the policy.

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

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