Inspection Report

23 May 2024

Orthoderm Clinic

Type of service: Independent Hospital – Day surgery cases only
Address: 2 Ballynahinch Road, Hillsborough, BT26 6AR
Telephone number: 028 9268 0940

Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/ The Independent Health Care Regulations (Northern Ireland) 2005 and Minimum Care Standards for Independent Healthcare Establishments

1.0 Service information

Organisation/Registered Provider: Orthoderm Ltd **Responsible Individual:** Mr Michael Eames	**Registered Manager:** Ms Emma Stinson, acting manager **Date registered:** Awaiting registered manager application
Person in charge at the time of inspection: Ms Emma Stinson	
Categories of care: Acute Hospital (Day Surgery) - AH(DS) Private Doctor - PD Endoscopy - PT(E)	
Brief description of how the service operates: Orthoderm Clinic is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with prescribed techniques or prescribed technology: establishments providing endoscopy services PT(E); private doctor (PD) and acute hospitals (day surgery only) AH (DS) categories of care. Orthoderm 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. Orthoderm Ltd is part of the Affidea Group which also owns and operates Hillsborough Private Clinic and Affidea Belfast, also registered with RQIA.	

2.0 Inspection summary

A short notice announced inspection was undertaken to Orthoderm Clinic which commenced with an onsite inspection on 23 May 2024 from 10.00 am to 5.00 pm and included a request for the submission of information electronically.

The onsite component of the inspection was completed on 23 May 2024 by three care inspectors. Feedback of the onsite inspection findings was delivered to Ms Stinson, acting manager and the clinical manager on the day of the inspection.

The electronic submission of additional documentation in relation to the premises aspect of the inspection was reviewed remotely by an RQIA estates inspector and feedback was provided to the registered person following the inspection.

This inspection focused on four main key themes: organisational and clinical governance; the safe practice for provision of day surgery/endoscope services; staffing arrangements and estates management.

Examples of good practice were evidenced in patient safety in respect of the management of the patients' care pathway; and engagement to enhance the patients' experience.

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

3.0 How we inspect

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

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

- notifiable events since the previous care inspection
- the registration status of the hospital
- written and verbal communication received since the previous care inspection
- the previous care inspection report

One week prior to the onsite inspection the hospital was provided with a list of specific documents requesting items to be reviewed remotely in respect of the maintenance of the premises and grounds. These items were to be sent electronically to our estates inspector on or before 31 May 2024 for review remotely.

The inspection the team undertook a tour of the premises and the inspection was facilitated by Ms Stinson and the clinical manager.

During the inspection we spoke with Ms Stinson, acting manager who is also the human resources (HR) and compliance manager; the clinical manager; the clinic operations manager, Affidea Group and a senior nurse.

The information obtained is then considered before a determination is made on whether the establishment is operating in accordance with the relevant legislation and minimum standards.

Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the quality improvement plan (QIP).

4.0 What people told us about the service

Posters were issued to Orthoderm Clinic by RQIA prior to the inspection inviting clients and staff to complete an electronic questionnaire.

Two patients submitted responses and both respondents indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. Both respondents also indicated that they were very satisfied with each of these areas of their care.

Through discussion with a number of staff who have differing roles and responsibilities it was determined that staffing levels and morale were good with evidence of good multidisciplinary team working and effective communication between staff.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

The last inspection to Orthoderm Clinic was undertaken on 16 May 2022; no areas for improvement were identified.

5.2 Inspection findings

5.2.1 Organisation and clinical governance

Organisational Governance

As previously stated, Orthoderm Clinic is part of the Affidea Group which also owns and operates Hillsborough Private Clinic and Affidea Belfast. The inspection team were informed that the Affidea Group had recently undertaken internal restructuring. Within the new organisational structure, the clinical manager has responsibility for the day to day management of Orthoderm Clinic and Hillsborough Private Clinic which is located close by and is supported by the HR and compliance manager. The clinic operations manager has overall responsibility for Orthoderm Clinic, Hillsborough Private Hospital and Affidea Belfast.

It was confirmed that Mr Michael Eames continues as the responsible individual and medical director. Inspectors were informed that a new registered manager application will be submitted to RQIA in respect of the new clinic manager at the earliest opportunity.

Various aspects of the organisational systems were discussed with Ms Stinson and the clinical manager. A range of minutes were reviewed which identified that regular senior management team (SMT) governance meetings take place and evidenced that information is disseminated to staff via team leads either face to face or via emails. It was evidenced that the SMT governance meetings are held bi monthly and are attended by the medical directors, Ms Stinson, the clinical manager and departmental leads.

Agenda items include clinical governance, quality, risk, compliance and audit. Meeting minutes detail the outcomes with time limited actions and the identified persons to address each action point and provide assurance to the responsible individual and medical directors. In addition, weekly operational meetings are held and are attended by Ms Stinson, the clinical manager and the bookings and admissions lead staff member.

Documents viewed during the inspection described a wide range of activities which included: monitoring of customer satisfaction; the outcomes of key performance indicators (KPI); audits and incident management and trend analysis. Audits were used to assess performance against agreed standards as part of a rolling audit programme. Audits included hand hygiene, environmental, infection prevention and control and the use of flexible scopes. Mechanisms were in place to ensure results from the audits were reviewed during the Medical Advisory Committee (MAC) meetings and shared with all staff.

Where the business entity operating a registered establishment is a corporate body or partnership or an individual owner who is not in day to day management of the service, unannounced quality monitoring visits by the registered provider, or person acting on their behalf, must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. It was established that six monthly unannounced quality monitoring visits are undertaken by Mr Eames and the reports are shared with Ms Stinson and the clinical manager and presented at the MAC meeting and the two monthly SMT governance meetings.

Policies and procedures were available for staff reference and discussion with Ms Stinson and the clinical manager confirmed that a structure is in place to ensure that policies are being reviewed in a systematic manner. Staff reported they were aware of the policies and how to access them.

A procedure for the dissemination and implementation of regional and national guidance, urgent communications, safety alerts and notices was in place to ensure all patient safety communications received were distributed and actioned appropriately in a timely manner.

The communication of information is also provided at staff meetings, by email and also by information displayed on staff information boards.

It was also demonstrated that there were robust governance systems in place regarding the monitoring of medical, nursing and other health care professional bodies' registration status.

Staff who spoke with us were able to describe their roles and responsibilities and confirmed that there were good working relationships with managers, who were responsive to any suggestions or concerns raised.

Examination of insurance documentation confirmed that insurance policies were in place.

The RQIA certificate of registration was up to date and displayed appropriately.

Clinical and medical governance

Clinical governance within Orthoderm Clinic was overseen by the MAC and directors meeting. Terms of reference for the MAC were in place and these have been developed in accordance with Standard 30 of the Minimum Care Standards for Independent Healthcare Establishments (2014). The chief executive officer of the Affidea Group also attends these meetings. It was evidenced that the MAC meetings have standing agenda items and are used as a forum to discuss clinical governance issues, the appointment and renewal of practising privileges agreements, the review of performance indicators, corrective action in relation to adverse clinical incidents and any other untoward event or near miss, the outcome of completed audits, staff training compliance figures, the review of complaints/compliments and also estates management matters. These meetings were being undertaken on a quarterly basis in line with the criteria set out in Standard 30.

A team of consultant surgeons who have specialist qualifications and skills work in Orthoderm Clinic.

Orthoderm Clinic monitors individual consultant files, checking registration with the General Medical Council (GMC), professional indemnity and appraisals.

In accordance with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. As part of the revalidation process, responsible officers (RO) make revalidation recommendations 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 the areas of the doctor's work. It was established that all medical practitioners working in the clinic have a designated RO. A discussion was held around how concerns would be raised regarding a doctor's practice with the MAC and within the wider Health and Social Care (HSC) sector. Orthoderm Clinic has established links with ROs of the doctors working in the organisation.

A small number of consultants are considered to be wholly private doctors as they are not affiliated with the HSC sector in Northern Ireland (NI) and are not on the General Practitioner's (GPs) performer list in NI. Review of the three consultants' details confirmed evidence of the following:

- confirmation of identity
- current GMC registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and the GMC
- ongoing annual appraisal by a trained Medical Appraiser
- an appointed RO
- arrangements for revalidation

We reviewed the arrangements for the oversight and recording of induction and on-going training for consultants to ensure all consultants working in Orthoderm Clinic receive mandatory training and other training, supervision and appraisal in accordance with best practice guidance. A review of records demonstrated that the clinic retains a copy of each consultant's annual appraisal document.

Appraisal is a key part of revalidation and includes the appraisee providing evidence of their individual continuing professional development (CPD) activities undertaken in accordance with the GMC Good Medical Practice.

Whilst it is the responsibility of GMC registrants to keep up to date with their CPD activities, the CPD learning activities may not meet with legislative mandatory training such as fire safety, safeguarding adults, children and young people, infection prevention and control and resuscitation.

Discussion with Ms Stinson and a review of records demonstrated that a staff training matrix was in place that included all staff and provided up to date information on staff training compliance. A review of the matrix evidenced a high rate of compliance in all areas of training and where training was due for renewal or had expired, these were highlighted for follow up. It was noted that in respect of consultant's training, compliance rates were not as high as other staff members. Ms Stinson informed us that a fresh approach has been taken to ensure consultant's complete Orthoderm Clinic's mandatory training requirements and this begins at the point of a consultant making application to work in Orthoderm Clinic. The training matrix demonstrated that progress is being made in this regard. As previously discussed, training compliance rates are included in the quarterly MAC meetings.

A review of sample of staff personnel files confirmed that a record of induction and individual training records and certificates were retained to verify that training had been successfully completed.

Practising Privileges

The only mechanism for a medical practitioner to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the hospital. Ms Stinson informed us that that all medical practitioners who work in Orthoderm Clinic work under a practising privileges agreement.

A detailed policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended. It was noted that the practising privileges application now includes a requirement to demonstrate completion of specific areas of mandatory training.

A review of a sample of records evidenced that there was a written practicing privileges agreement between each private doctor and Orthoderm Clinic setting out the terms and conditions which had been signed by both parties.

It was noted that the practising privileges agreements had been reviewed within the previous two years. They clearly stated each consultant's scope of practice and had been signed by both parties.

As previously discussed, practising privileges matters are discussed and reviewed during the MAC meetings.

Discussion with the Orthoderm Clinic management team demonstrated that good oversight arrangements of the granting of practicing privileges agreements were in place and provided assurance of robust medical governance arrangements within the organisation.

Quality assurance

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals.

Significant incidents and themes reported are discussed by the organisation's quality and safety committee and at the MAC meetings.

There was a robust programme for internal audit to monitor compliance with policies and processes. Audits are completed monthly, quarterly and annually as per the Orthoderm Clinic audit schedule. The results are monitored by the local and regional management team and actions identified for improvement are embedded into practice. If required, an action plan is developed to address any shortfalls identified during the audit process.

A system was also in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

Notifiable Events/Incidents

A policy for the management and reporting of clinical risks, incidents and near misses and a policy for the management of national safety alerts were in place.

Orthoderm Clinic management team confirmed that any learning from incidents would be discussed with staff. There was a process in place 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 at the earliest opportunity.

As previously mentioned significant incidents and themes reported are discussed at the bi-monthly SMT governance meetings and quarterly MAC meetings.

Complaints Management

A copy of the complaints procedure was available in the hospital and was found to be in line with the relevant legislation and Department of Health (DoH) guidance on complaints handling.

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

A review of the complaints log confirmed that all complaints received since the previous inspection had been investigated and responded to appropriately to include details of all communications with complainants; the result of any investigation; the outcome and any action taken. A complaints audit was unavailable on the day of inspection however; the most recent complaints audit was submitted to RQIA following the inspection. It was found to reflect themes emerging from complaints analysis and any action taken to address themes had been recorded. Learning is disseminated across all staff groups to drive improvement in the quality of this service, which staff confirmed during the inspection.

The management of complaints is reviewed on a weekly basis with an over-arching quarterly audit of complaints to identify trends or themes emerging. The quarterly audit of complaints is included as standing agenda item for the MAC meetings.

Risk Management

Systems are in place to support good risk management within the hospital. This ensures that the likelihood of adverse incidents, risks and complaints are minimised by effective identification, prioritisation, treatment and management.

Risks were documented, collated and tracked through the use of a risk register which provided assurance about the effective identification and management of risk.

Overall, the governance structures within the hospital provided the required level of assurance to the responsible individual and the Affidea Group.

5.2.2 Are there safe practices in place for the provision of day surgery/endoscopy services?

The inspectors reviewed the arrangements for the provision of day surgery and endoscopy services in the hospital outlined under their statement of purpose and categories of care. The review of these arrangements evidenced that the service intends to operate in accordance with best practice and national standards to ensure care delivery is safe and effective. It was confirmed that the hospital provides a limited day surgical service and endoscopy service (cystoscopy only) under local anaesthesia as appropriate. No procedures are undertaken using intravenous sedation or using a general anaesthetic.

A number of consultants from orthopaedics, plastic surgery, dermatology and urology undertake minor surgical procedures. It was confirmed that surgical services are largely provided mainly to adults with a very limited minor paediatric surgical service offered. The provision of a minor paediatric surgical service was discussed in relation to the adherence to best practice and professional standards for paediatric surgery. It was advised to review the provision of paediatric surgical services to ensure compliance with relevant standards. Following the inspection, the management informed RQIA that the paediatric surgical service will be reviewed at the next MAC meeting in July 2024.

The scheduling of patients for surgical procedures is co-ordinated by the clinical co-ordinator, the consultant and the administration office. The theatre lists take into account the individual requirements of the patient, the type of procedure to be performed, availability of equipment, staffing levels required, and any associated risks.

The patient will be sent information about the procedure and any preparation necessary in advance, together with the consent form.

The consent process is completed by the consultant carrying out the procedure as part of the admission process. The consented patient is then escorted to the treatment room or endoscopy suite.

There will be an identified member of nursing staff, with relevant experience, in charge during all procedures. Staff will complete a surgical safety checklist based on World Health Organisation (WHO) guidance and will complete the surgical checklist and compliance will be routinely audited through the hospital's auditing process.

It was confirmed that patients are observed during and after the procedure by appropriately trained staff. Patients are discharged in accordance with the discharge criteria by the nursing staff. It was confirmed that if there were any concerns about the patient's condition, the consultant would be immediately informed for ongoing management. Patients are provided with clear post procedure advice, information on follow up and details of who to contact in the event of a post treatment emergency.

Surgical registers were in place and were found to be well recorded in accordance with regulation. It was confirmed that no surgical assistants were used in the hospital.

Supplies of sterile instrument packs and reprocessed endoscopes are obtained from an approved sterile services department under contract from a health and social care trust. There are robust measures in place to monitor the traceability of all surgical instruments used in the clinic. Clinical equipment was evidenced to be clean and fit for purpose, and traceability labels were used to identify when equipment had been cleaned.

A wide range of comprehensive policies and procedures are in place to ensure that safe and effective care is provided to patients, which are in accordance with good practice guidelines and national standards.

Three completed day surgery patient care pathways and endoscopy patient care pathways were reviewed and were found to provide a framework for clear records of admission, medical history, infection prevention and control status, medication, observations on admission, pre-procedure checklist, WHO surgical checklist, intra- procedure details, traceability details, post procedure observations and a discharge record. It was noted that, whilst a completed discharge record was in place in the patient records reviewed, there was a section relating to discharge that had not been completed. It was advised to complete this section as necessary or note on the record that it is not applicable. Management were receptive to advice and gave assurances on this matter.

There were procedures for the collection, labelling, storage, preservation, transport and administration of specimens. However, staff clearly described detailed procedures for the management of specimens and the procedure for reporting results to the appropriate clinical staff and GPs which was not fully reflected in the written procedures. Following the inspection, the pathology specimen procedure was amended to fully reflect practice as described by staff. It was confirmed there is a contract in place with a pathology laboratory service. The pathology services are subject to internal audit.

An emergency trolley is located in theatre and checked daily by nursing staff. Emergency medicines, oxygen and equipment were all in date and clear stock control is in place. Medical emergencies were discussed including the management of massive blood loss emergency. It was noted that there was no separate massive blood loss tray in place. It was advised to establish a massive blood loss tray and following the inspection RQIA received confirmation a massive blood loss tray would be established.

As outlined previously a limited paediatric minor surgery service is provided, and it was noted that paediatric emergency medicines and equipment are available within the emergency trolley, however, these are not stored separately from the adult emergency drugs and equipment. It was advised that they provide a separate paediatric medical emergency grab bag/tray to allow ease of access to the paediatric emergency drugs and equipment in the event of a paediatric medical emergency. Management gave assurances that they would provide a separate paediatric medical emergency grab bag or tray with the involvement of appropriate medical staff.

It was determined that safe practices were in place for the day surgery and endoscopy services.

5.2.3 Does the hospital have appropriately qualified and skilled staff in place?

The arrangements for the recruitment and selection of staff were reviewed. A recruitment policy and procedure was in place in keeping with legislation and best practice guidance.

A staff register was available to review and was found to be up to date and contained staff details in keeping with legislation.

It was evidenced that, in the main, staff were recruited and employed in accordance with relevant employment legislation and best practice guidance. Six staff personnel files were reviewed, inclusive of newly recruited staff, and evidenced that most information required by legislation was obtained and retained in the files. It was noted that the criminal declaration was missing from one staff record and a declaration of physical and mental health was missing from five of the staff records. An induction programme was available for five of the six staff records reviewed. Following the inspection all the records unavailable during the inspection were submitted to RQIA.

A review of duty rotas and discussion with staff evidenced that there were sufficient staff in various roles to fulfil the needs of the clinic and patients.

A review of a sample of records and discussion with staff evidenced that supervision has been completed on a regular basis and appraisals had been completed on an annual basis. Staff reported that they were well supported and fully involved in discussions about their personal and professional development.

As previously discussed a training matrix is maintained and was evidenced during the inspection, with training in date and a rolling programme of updates evidenced. Induction programme templates were in place relevant to specific roles within the hospital.

Staff told us that there were good working relationships throughout the hospital and we found clear evidence of multidisciplinary working.

Ms Stinson and the clinical manager confirmed that there is a system in place to review the registration details of all health and social care professionals with their professional bodies. Records were available for review in this regard.

It was determined that appropriate staffing levels were in place to meet the needs of patients and the staff were suitable trained to carry out their duties.

5.2.4 Estates

The following documentation was reviewed in relation to the maintenance of the premises including the mechanical and electrical installations:

- 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 of fire drills undertaken
- Lifting Operations and Lifting Equipment Regulations (LOLER) 'Thorough Examination' reports of the premises' passenger lift
- condition report for the premises' fixed wiring installation
- gas safe certification
- report for the formal testing of the premises portable electrical appliances
- legionella risk assessment
- service records, validation checks and audits for the premises' critical ventilation systems

The premises general mechanical and electrical systems are currently being serviced and maintained in accordance with current regulations and best practice guidance.

The most recent legionella risk assessment was undertaken on 7 December 2023 and no significant actions were noted. Suitable control measures and temperature monitoring of the premises' hot and cold water systems was in place with records being maintained as recommended. Water samples analysed on 7 December 2023 did not detect any legionella bacteria in the premises' hot and cold water systems.

The current fire risk assessment was reviewed on 9 May 2024. The overall assessment was assessed as 'tolerable' and no significant findings were identified. The most recent fire drill for the premises was undertaken on 12 October 2023. Any issues identified during this drill were immediately followed up by management and advice issued to staff.

The premises' critical 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.

It was determined that procedures are in place for maintaining the premises, grounds, engineering services and equipment in line with legislation, current standards of best practice and manufacturer's and supplier's guidance and that these are regularly reviewed and updated.

6.0 Quality Improvement Plan/Areas for Improvement

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Ms Stinson, acting manager and the clinical manager, as part of the inspection process and can be found in the main body of the report.

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