The Regulation and Quality Improvement Authority

RQIA Provider Guidance 2024-2025

Independent Hospital

Refractive Eye Surgery/Lasers

What we do

The Regulation and Quality Improvement Authority (RQIA) is the independent body that regulates and inspects the quality and availability of Northern Ireland's health and social care (HSC) services. We were established in 2005 under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to drive improvements for everyone using health and social care services.

Through our programme of work, we provide assurance about the quality of care; challenge poor practice; promote improvement; safeguard the rights of service users; and inform the public through the publication of our reports. RQIA has four main areas of work:

- We register and inspect a wide range of independent and statutory health and social care services.
- We work to assure the quality of services provided by the Strategic Planning and Performance Group (SPPG), HSC trusts and agencies - through our programme of reviews.
- We undertake a range of responsibilities for people with mental ill health and those with a learning disability.
- We support establishments and service providers to improve the service they deliver.

All work undertaken by RQIA is focused on the following four domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well led?

RQIA registers, inspects and supports a wide range of health and social care services. These include: nursing, residential care, and children's homes; domiciliary care agencies; day care settings/centres; independent hospitals; independent clinics; independent medical agencies; nursing agencies; residential family centres; adult placement agencies; voluntary adoption agencies, school boarding departments and young adult supported accommodation (inspected only).

The four domains

How we will inspect

We will inspect every refractive eye service at least annually. Our inspectors are most likely to carry out an announced inspection, however from time to time we may carry out an unannounced inspection in response to concerns that may be raised with us.

When we inspect a refractive eye service, we aim to provide assurances in respect of the standard, quality and safety of services delivered. We do this by:

- Seeking the views of the people who use the service, or their representatives.
- Talking to the management and other staff on the day of the inspection.
- Examining a range of records including care records, incidents, complaints and policies.
- Providing feedback on the day of the inspection to the registered person/manager on the outcome of the inspection.
- Providing a report of our inspection findings and outline any areas for quality improvement.

Our inspections are 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
- The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2022
- The Department of Health, (DOH) Minimum Care Standards for Healthcare Establishments July 2014

Provider guidance in respect of the maintenance and upkeep of the premises and the management of medicines are also available on our website and are currently under review. These documents should be reviewed to ensure compliance with the minimum standards and legislation.

Should you have additional categories of care, please ensure that you review and adhere to the relevant provider guidance document i.e. private doctor (PD).

What we look for when we inspect

To help us to report on whether the care is safe, effective, compassionate and well led, we will look for evidence against the following indicators.

Is care safe?

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

Indicator S1
There are, at all times, suitably qualified, competent and experienced persons working in the service in such numbers as are appropriate for the health and welfare of service users.

Examples of evidence

Staffing

- There are sufficient numbers of staff in various roles to fulfil the needs of the establishment and patients.
- There are arrangements in place for maintaining a record of the shifts worked by each staff member to include a record of the hours worked by each person.
- There is an induction programme in place appropriate to the role.
- A system is in place to ensure staff receive annual appraisals and records are retained.
- A system is in place to ensure all staff receive appropriate training to fulfil the duties of their role including professional body Continuing Professional Development (CPD) recommendations and RQIA training guidance records should be retained.
- There are arrangements for monitoring the professional body registration status of all clinical staff, records should be retained for inspection.
- There are arrangements in place for monitoring the professional indemnity of all staff who require individual indemnity cover, records should be retained for inspection.
- Evidence that each private doctor has confirmation of identity, current General Medical Council (GMC) registration, professional indemnity insurance, qualifications in line with service provided; evidence of ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC.
- Evidence that each private doctor has an appointed responsible officer (RO).
- Arrangements are in place to link into the wider system of RO's for doctors with practising privileges who work in other parts of the Northern Ireland (NI) healthcare system or in other healthcare systems beyond NI.
- Arrangements are in place to ensure that any newly appointed private doctor has notified their aligned RO of their new position.
- Evidence of arrangements for revalidation.
- Each private doctor is aware of their responsibilities under GMC Good medical practice 2024 and 'Good practice in prescribing and managing medicines and devices'.
- There is a system in place to ensure that all medical practitioners adhere to the Professional Standards for Refractive Surgery 2022 (rcophth.ac.uk)
- Arrangements are in place to ensure the full appraisal document for each medical practitioner is reviewed and scrutinised by the registered person before granting or renewing practising privileges and a record retained.

Laser authorised operators

- Refractive eye surgical procedures are carried out by trained medical practitioners (clinical authorised operators).
- A register of authorised operators for the laser is maintained and kept up to date.

Recruitment and selection

- Staff have been recruited in line with Regulation 19 (2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.
- There is a written policy and procedure for staff recruitment in keeping with Regulation 19 (2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.
- Staff personnel files are in keeping with 19 (2) Schedule 2, as amended.
- Enhanced AccessNI checks are received prior to all new staff commencing work.
- All staff involved in Regulated Activity with adults or Regulated Activity with children must have their enhanced AccessNI disclosure checked against the barred list in keeping with AccessNI code of practice.
- Recruitment and selection records should be retained for three years from the date of last entry in keeping with Regulation 21 (3) Schedule 3 Part II.
- An up to date staff register should be maintained and retained in keeping with Regulation 21 (3) Schedule 3 Part II.

Indicator S2
The service promotes and makes proper provision for the welfare, care and protection of service users.

Examples of evidence

Safeguarding- Adults

- Policies and procedures are in line with the regional Adult Safeguarding Prevention and Protection in Partnership policy (July 2015) and Northern Ireland Adult Safeguarding Partnership operational handbook June 2017
- The establishment has identified an adult safeguarding champion (if required).
- There is an identified safeguarding lead and staff are aware of who the safeguarding lead is.
- All staff receive the relevant level of training as outlined in RQIA training guidance.
- Staff training should be in keeping with Northern Ireland Adult Safeguarding Partnership Training Strategy 2013 (revised 2016)
- Staff are knowledgeable about adult safeguarding and are aware of their obligations in relation to raising concerns.
- All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation; written records must be retained.
- Where shortcomings are highlighted as a result of an investigation, learning arising should be assessed, implemented and quality assured.
- Staff are familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.

Safeguarding -Children

- Policies and procedures are in line with the regional Co-operating to Safeguard Children and Young People in Northern Ireland, (August 2017) and Safeguarding Board for Northern Ireland (SBNI) Procedures Manual (November 2017).

- There is an identified safeguarding lead and staff are aware of who the safeguarding lead is.
- All staff receive the relevant level of training as outlined in RQIA training guidance.
- Staff training should be in keeping with SBNI Child Safeguarding Learning and Development Strategy and Framework 2020 – 2023.
- Staff are knowledgeable about safeguarding children and are aware of their obligations in relation to raising concerns.
- All suspected, alleged or actual incidents of abuse are fully and promptly referred to the relevant persons and agencies for investigation in accordance with procedures and legislation; written records must be retained.
- Where shortcomings are highlighted as a result of an investigation, learning arising should be assessed, implemented and quality assured.
- Staff are familiar with their responsibilities and know how to appropriately recognise poor practice and raise concerns.

Laser safety

- A laser safety file is in place which contains all of the relevant information in relation to laser equipment.
- Medical treatment protocols are in place produced by a named registered medical practitioner who is trained and experienced in the relevant discipline within which treatment is provided.
- There is a system in place for the continuous review of the treatment protocol by the named registered medical practitioner.
- Local rules are in place that detail the normal operation of equipment.
- There is written confirmation of the appointment and duties of a certificated laser protection advisor (LPA) that is renewed annually.
- Written confirmation of the appointment and duties of a person who has overall onsite responsibility for safety during laser procedures is in place.
- Laser authorised operators have up to date training in laser safety and their use that complies with current legislative requirements and professional guidelines.
- Clinical and non-clinical authorised operators have signed to indicate that they have accepted and understood the local rules and medical treatment protocols drawn up for the use of lasers.
- All support staff have up to date awareness training in laser safety.
- A register is maintained every time the laser is operated.

Indicator S3
There are systems in place to ensure that unnecessary risks to the health, welfare or safety of service users are identified, managed and where possible eliminated.

Examples of evidence

Management of medical emergencies

- A policy in relation to the management of medical emergencies is in place (to include a risk assessment, training arrangements, provision of equipment, emergency medication, checking procedures, how to summon help, incident documentation and staff debriefing).
- Procedures in relation to the management of medical emergencies are in place.
- Emergency medicines and equipment are available in accordance with British National Formulary (BNF) and the Resuscitation Council (UK)
- A robust system is in place for checking expiry dates of medicines and equipment by an identified individual.

- Management of a medical emergency is included in induction and update training is provided annually.
- Staff have knowledge and understanding of managing a medical emergency.

Infection prevention control and decontamination procedures

- The environment is clean and clutter free.
- Infection prevention and control (IPC) policies and procedures are in place in keeping with The Northern Ireland Regional Infection Prevention and Control Manual.
- Staff have knowledge and understanding of IPC measures in line with best practice including the decontamination of laser machines.
- There are cleaning schedules in place.
- All staff receive training in IPC that is commensurate with their role and responsibilities.

COVID-19

- Staff should have knowledge and understanding and adhere to the most up to date DoH guidance.
- Arrangements are in place to routinely review the websites listed below:
  Public Health Agency (PHA) Covid-19 webpage:
  https://www.publichealth.hscni.net/covid-19-coronavirus
  Northern Ireland (NI) direct Covid-19 webpage:
  https://www.nidirect.gov.uk/campaigns/coronavirus-covid-19

Laser safety

- There are arrangements in place to ensure that all Class 3B/4 lasers meet British Standard 60-825-1 as specified within The Independent Health Care Regulations (Northern Ireland) 2005.
- There is a system in place to ensure that the safe use of lasers is in accordance with the Medicines & Healthcare products Regulatory Agency (MHRA) Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices guidance document.
- A risk assessment has been undertaken by the LPA which is reviewed in agreement with the LPA and provider at least every three years.
- For all lasers with a key switch, there are formal written arrangements for the safe custody of the key and/or key code, separate from the equipment. The key is not left unattended with the equipment.
- Protective eyewear is available for the patient if needed and authorised operator in accordance with the local rules.

Risk management

- There are risk management procedures in place.
- All risks in connection with the establishment, treatment and services are identified, assessed and managed.
- Arrangements are in place to provide evidence of appropriate review of risk assessments.
- Any findings/learning arising from risk assessments should be implemented and assured.
- An overarching corporate risk register is in place which details the measures in place to mitigate and control identified risks.

Indicator S4
The premises and grounds are safe, well maintained and suitable for their stated purpose.

Examples of evidence

Environment

- The establishment is clean, clutter free, warm and pleasant.
- There are no obvious hazards to the health and safety of patients and staff.
- There are arrangements in place in relation to maintaining the environment (e.g. servicing of lift/gas/boiler/fire detection systems/fire-fighting equipment/fixed electrical wiring installation/ legionella risk assessment).
- Arrangements are in place to ensure that environmental risk assessments are reviewed on an annual basis. Any findings/learning arising from risk assessments should be implemented and assured.

Laser equipment and controlled areas

- The area around lasers is controlled to protect other persons while treatment is in progress.
- The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.
- No other laser is in use in the same controlled area at the same time.
- Warning signs that comply with current legislation, directives and standards are displayed on the equipment and on the outside of doors to the controlled area (and removed when the equipment is not in use).
- The door of the treatment room is locked when the laser equipment is in use which can be opened from the outside in the event of an emergency.
- Lasers are serviced and maintained in accordance with manufacturer's instructions to ensure they are operating within their design specification. A detailed record of all servicing and repairs is kept.

Is care effective?

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

Indicator E1
The service responds appropriately to and meets the assessed needs of the people who use the service.

Examples of evidence

Care pathway

- All patients have an initial consultation with a fully qualified optometrist.
- All patients have a pre-operative consultation with a consultant ophthalmologist (surgeon).
- There are arrangements in place to ensure that the establishment adheres to the Refractive-Surgery-Patient-Checklist-April2017.pdf (rcophth.ac.uk).
- There is a clear patient care pathway recorded within care records to include: initial consultation, pre-operative, intra-operative and post-operative care.
- There is evidence of a patient completed health questionnaire within the care records.
- There is evidence of a signed consent form within the care records which clearly outlines associated risk and complications of surgery.
- Patients are provided with post-operative instructions.

- Patients are provided with information on emergency on-call arrangements.
- Systems are in place to review the patient following surgery, one day, one week, one month, three months and longer if necessary.
- There are systems in place for the optometrist to refer patients directly to a consultant ophthalmologist if necessary post-operatively.
- Record keeping is in accordance with legislation, standards and best practice guidance; GMGR records management.
- A policy and procedure is available which includes the arrangements in respect of the creation, storage, recording, retention and disposal of records.
- Records are securely stored (electronic and hard copy).
- The establishment is registered with the Information Commissioners Office (ICO).
- The establishment has arrangements in place to comply with the General Data Protection Regulation (GDPR).
- A patient register in keeping with Schedule 3 Part II of the Independent Health Care Regulations (Northern Ireland) 2005 is maintained and kept-up to date.

Indicator E2
There are arrangements in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals.

Examples of evidence

- A range of audits, including clinical audits, are undertaken routinely and any actions identified for improvement are implemented into practice.
- Arrangements are in place to escalate shortfalls identified during the audit process through the establishment's governance structures.

Indicator E3
There are robust systems in place to promote effective communication between service users, staff and other key stakeholders.

Examples of evidence

Communication

- There is written information for patients that provides a clear explanation of any treatment provided and includes effects, side-effects, risks, complications and expected outcomes.
- Information is written which is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.
- Treatment and care services are planned and developed with meaningful patient involvement; facilitated and supported as appropriate; and provided in a flexible manner to meet individual and changing requirements.
- Advertising and marketing campaigns comply with guidance issued by professional bodies and the appropriate regulatory body.
- There is an open and transparent culture that facilitates the sharing of information.
- Patients are aware of who to contact if they want advice or have any issues/concerns.
- Staff meetings are held on a regular basis and minutes retained.
- Staff can communicate effectively.
- Learning from complaints/incidents/near misses is effectively disseminated to staff, implemented and assured.

- The procedure for delivering bad news to patients, their families and other significant people is developed in accordance with guidance such as Breaking Bad News regional guidelines 2003.

Is care compassionate?

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

Indicator C1
There is a culture/ethos that supports the values of dignity and respect, independence, rights, equality and diversity, choice and consent of service users.

Examples of evidence

- Staff can demonstrate how confidentiality is maintained.
- Staff can demonstrate how consent is obtained.
- Staff are aware of their responsibilities should a patient refuse treatment.
- There is a policy and procedure on obtaining informed consent in line with GMC guidance on consent.
- There is a policy and procedure on maintaining confidentiality which is regularly assured.
- There is a suitable location for private consultation.
- There are arrangements in place to assist patients with a disability or who require extra support.

Dignity, respect and rights

- Patient's privacy and dignity is respected at all times.
- Patients' rights to make decisions about care and treatment are acknowledged and respected.
- Patients are treated and cared for in accordance with legislative requirements for equality and rights.

Mental capacity

- There are systems and processes in place to identify where there may be evidence of lack of mental capacity.
- There is a model of consultation, which facilitates an assessment of capacity in line with legal expectations.

Indicator C2
Service users are listened to, valued and communicated with, in an appropriate manner.

Examples of evidence

Informed decision making

- There are arrangements in place to support patients to make informed decisions.
- There are arrangements for providing information in alternative formats/interpreter services, if required.
- The consultant ophthalmologist who is to undertake the surgical procedure visits the patient and obtains consent for the proposed surgery and ensures the consent form(s) are signed prior to surgery.

- Information regarding services provided is prepared in line with the GMC guidance document; Good medical practice-2024.
- Information provided includes the costs of treatments.
- Information is written in plain English.

Indicator C3
There are systems in place to ensure that the views and opinions of service users, and or their representatives, are sought and taken into account in all matters affecting them.

Examples of evidence

Patient consultation

- Patient consultation (patient satisfaction survey) about the standard and quality of care and environment is carried out at least on an annual basis.
- The results of the consultation are collated to provide a summary report.
- The summary report is made available to patients and a subsequent action plan is developed to inform and improve services.
- RQIA staff/patient questionnaire responses are reviewed and used to improve services.

Is the service well led?

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

Indicator L1
There are management and governance systems in place to ensure the overall quality and safety of services provided.

Examples of evidence

Governance arrangements

- Where the entity operating the establishment is a corporate body or partnership or an individual owner who is not in day to day management of the establishment, in accordance with Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, arrangements are in place to ensure the registered person/nominated representative monitors the quality of services and undertakes an unannounced visit to the premises at least six monthly and produces a report of their findings (where appropriate).
- There are arrangements in place for policies and procedures to be reviewed at least every three years.
- Policies are centrally indexed, a date of implementation and planned review is recorded and they are retained in a manner which is easily accessible by staff.
- Arrangements are in place in relation to medical governance in accordance with the GMC guidance document: Effective clinical governance for the medical profession: A handbook for organisations employing, contracting or overseeing the practice of doctors'.
- Arrangements are in place to ensure that all surgical procedures are undertaken per the guidance and standards produced by The Royal College of Ophthalmologists.
- Arrangements are in place to provide evidence of an appropriate review of risk assessments e.g. legionella, fire, Control of Substances Hazardous to Health (COSHH).

Complaints

- The establishment has a complaints policy and procedure in accordance with the relevant legislation and DoH Guidance in relation to the Health and Social Care Complaints Procedure (Updated April 2023).
- There are clear arrangements for the management of complaints and records are kept of all complaints and these include details of all communications with complainants, investigation records, the result of any investigation, the outcome and the action taken.
- Staff know how to receive and deal with complaints.
- Arrangements are in place to audit complaints to identify trends and improve services provided.
- Themes emerging from complaints are analysed with input from other relevant governance committees and any themes identified are disseminated to all staff.
- Complaints are triaged to identify if there are any clinical issues which need to be further reviewed in line with Risk Management procedures.

Statutory notification of incidents and deaths to RQIA

- The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA.
- Incidents are effectively documented and investigated in line with legislation.
- All relevant incidents are reported to RQIA and other relevant organisations in accordance with legislation and procedures RQIA Statutory Notification of Incidents and Deaths.
- Arrangements are in place to audit adverse incidents to identify trends and improve service provided.

Equality

- The management have systems in place to consider equality for patients.

Indicator L2
There are management and governance systems in place that drive quality improvement.

Examples of evidence

Quality improvement

- There is evidence of a systematic approach to the review of available data and information, in order to make changes that improve quality, and add benefit to the organisation and patients.

Quality assurance

- Arrangements are in place for managing relevant alerts.
- Arrangements are in place for staff supervision and appraisal.
- There are procedures to facilitate audit, including clinical audit (e.g. records, incidents, accidents, complaints).
- Results of audits are analysed and actions identified for improvement are embedded into practice.

Indicator L3
There is a clear organisational structure and all staff are aware of their roles, responsibility and accountability within the overall structure.

Examples of evidence

- There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities of all areas of the establishment.
- Staff are aware of their roles and responsibilities and actions to be taken should they have a concern.
- The registered person/s have understanding of their roles and responsibilities as outlined in legislation.
- Patients are aware of the roles of staff and who to speak to if they need advice or have issues/concerns.
- The registered person is kept informed regarding the day to day running of the establishment.
- There are opportunities to raise staff awareness through training and education regarding equality legislation to recognise and respond to patients' diverse needs.

Medical advisory committee (MAC)

- There are written terms of reference for the MAC.
- The MAC meets quarterly as a minimum, and arrangements are in place for extraordinary meetings, as necessary.
- The MAC reviews information collated by the registered manager on adverse clinical incidents (broken down by speciality, procedure and by clinical responsibility) on a quarterly basis to include:

    - All deaths
    - All unplanned re-admissions
    - Adverse incidents
    - All unplanned transfers to other hospitals or clinics
    - Other relevant clinical incidents
    - Complaints and compliments

- The MAC advises on corrective action when necessary.
- The MAC advises the service on developments in clinical practice.
- The MAC assists the senior management team to assure and evidence safe practice.
- The MAC provides the expertise to discuss and if necessary challenge practice of individual medical practitioners.
- Minutes of MAC meetings accurately reflect discussions progressed, actions agreed and persons responsible for taking forward actions within agreed timescales.

Practising privileges

- There is a written agreement between the medical practitioner and the agency that sets out the terms and conditions of granting practising privileges.
- Practicing privileges agreements are reviewed at least every two years.
- There is a written procedure that defines the process for application, granting, maintenance and withdrawal of practising privileges.

Indicator L4
The registered person/s operates the service in accordance with the regulatory framework.

Examples of evidence

- The statement of purpose and patient guide are kept under review, revised when necessary and updated.
- Insurance arrangements are in place for public and employer's liability.
- Registered person/s respond to regulatory matters (e.g. notifications, reports/QIPs, enforcement);
- Any changes in the registration status of the service are notified to RQIA.
- The RQIA certificate of registration is on display and reflective of services provided.
- The establishment has the correct categories of registration in line with services provided and the legislation.

Indicator L5
There are effective working relationships with internal and external stakeholders.

Examples of evidence

- Arrangements are in place for staff to access their line manager.
- There are arrangements in place to support staff (e.g. staff meetings, appraisal and supervision).
- There are good working relationships and management are responsive to suggestions/concerns.
- There are arrangements for management to effectively address staff suggestions/concerns.
- There is a raising concern/whistleblowing policy and procedural guidance for staff.

Inspection reports

Our inspection reports will reflect the findings from the inspection. Where it is appropriate, a Quality Improvement Plan (QIP) will detail those areas requiring improvement to ensure the service is compliant with the relevant regulations and standards as a minimum. Where no areas for improvement are identified from the inspection this will be reflected in the report.

Once the inspection report is finalised and agreed as factually accurate, it will be made public on RQIA's website.

The Regulation and Quality Improvement Authority

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