



RQIA Provider Guidance 2017-2018

Independent Hospital Refractive Eye Lasers

www.rqia.org.uk

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 three 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 HSC Board, 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 inspect and report on the following four domains:

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

RQIA registers and inspects 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 health care; nursing agencies; independent medical 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 Independent Hospital – Refractive Eye Laser establishment 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.

During our inspections we will inspect and report on the following four domains:

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

When we inspect a refractive eye laser establishment, we aim to:

- Seek the views of the people who use the service, or their representatives. Talk to the management and other staff on the day of the inspection
- Examine a range of records including care records, incidents, complaints and policies
- Provide feedback on the day of the inspection to the manager on the outcome of the inspection; and
- Provide a report of our inspection findings and outline any areas for quality improvement where failings in compliance with regulations and/or standards are identified.

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 Department of Health, Social Services and Public Safety's (DHSPPS) Minimum Care Standards for Healthcare Establishments July 2014

What We Look For When We Inspect

To help us to report on whether the care is safe, effective and compassionate and whether the service is well led, we will look for evidence against the following indicators. The evidence listed for each indicator provides examples of what may be reviewed and should not be considered exhaustive.

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 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 mandatory training, records should be available for inspection
- 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

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. Policy should include: open recruitment process, advertising, application process, shortlisting, interview & selection process, issuing of job description & contract of employment, employment checks, references, employment history, AccessNI, health, professional qualifications
- Staff personnel files are in keeping with 19 (2) Schedule 2, as amended
- Enhanced AccessNI checks are received prior to new staff commencing work
- Recruitment and selection records should be retained in keeping with Regulation 21 (3) Schedule 3 Part II
- A staff register should be maintained up-to-date and retained for inspection 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**

- Policies and procedures are in line with the regional 'Adult Safeguarding Prevention and Protection in Partnership' policy (July 2015) and Adult Safeguarding Operational Procedures (2016), Co-operating to Safeguard Children and Young People in Northern Ireland, (2016) and Area Child Protection Committees' Regional Policy and Procedures, (2005)
- There are arrangements in place to identify the Adult Safeguarding Champion/Safeguarding Lead (delete as appropriate)
- There are arrangements in place to embed the new regional operational safeguarding procedures
- Staff are knowledgeable about safeguarding and are aware of their obligations in relation to raising concerns
- Safeguarding training is provided during induction and updated as necessary
- 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, additional identified safeguards are put in place
- Staff are aware of their obligations in relation to raising concerns about poor practice

Laser Safety

- Medical treatment protocol produced by a named registered medical practitioner who are trained and experienced in the relevant discipline within which treatment is provided is in place
- 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 details 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 source 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
- A laser safety file is in place which contains all of the relevant information in relation to laser equipment

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
- 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) and decontamination policies and procedures are in place
- Staff have knowledge and understanding of IPC measures in line with best practice including the decontamination of laser/Intense pulse light (IPL) machines
- There are cleaning schedules in place
- All staff receive training in IPC that is commensurate with their role and responsibilities

Laser Safety

- 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, separate from the equipment. The key is not left unattended with the equipment
- Protective eyewear is available for the patient and authorised operator in accordance with the local rules

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 by a competent person

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 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
- A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records
- Records are securely stored – electronic/hard copy
- The establishment is registered with the Information Commissioners Office (ICO)

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

Indicator E3

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

Examples of Evidence

- 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

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 patient's modesty, privacy and dignity is respected at all times
- Staff can demonstrate how confidentiality is maintained
- Staff can demonstrate how consent is obtained
- Discussion with staff and observation of interactions demonstrate patients are treated with dignity and respect
- There is a suitable location for private consultation
- Patients' rights to make informed choices about care and treatment are acknowledged and respected
- There are arrangements in place to assist patients with a disability or who require extra support
- There is a policy and procedure on confidentiality

Indicator C2

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

Examples of Evidence

- There are arrangements in place for involving patients to make informed decisions
- There are arrangements for providing information in alternative formats/interpreter services, if applicable
- 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
- There is capacity for private consultation

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
- An action plan is developed to inform and improve services provided, if appropriate
- RQIA staff/patient questionnaire responses support the outcome that compassionate care is in place

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 meet the needs of service users.

Examples of Evidence

Governance Arrangements

- The registered person 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 to review 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 DHSSPS guidance on complaints handling
- There are clear arrangements for the management of complaints
- 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
- Information from complaints is used to improve the quality of services
- Staff know how to receive and deal with complaints
- Arrangements are in place to audit complaints to identify trends and enhance service provision

Incidents

- 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

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 practice
- 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 with if they need advice or have issues/concerns
- The registered person is kept informed regarding the day to day running of the practice

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
- Practising 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 - public and employers 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
- RQIA certificate of registration is on display and reflective of service provision
- 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

- There is a raising concern/whistleblowing policy and procedural guidance for staff
- 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)
- Discussion with staff confirmed that there are good working relationships and that management are responsive to suggestions/concerns
- There are arrangements for management to effectively address staff suggestions/concerns

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. Where no areas for improvement are identified from the inspection this will be reflected in the report.

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

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



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