The Regulation and Quality Improvement Authority

Inspection Report

28 November 2024

SpaMedica Belfast

Type of service: Independent Hospital – Laser Eye Surgery
Address: Ground Floor Data Works, Link Building Two, Kings Hall, Upper Lisburn Road, Belfast, BT9 6GU
Telephone number: 0330 0584 280

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 the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

1.0 Service information

Organisation/Provider: SpaMedica Limited **Responsible Individual:** Mr Simon Shepherd	**Registered Manager:** Mrs Carly Morrow **Date registered:** 21 October 2022
Persons in charge at the time of inspection: Mr Simon Shepherd Mrs Carly Morrow	
Categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor AH (DS) Acute hospitals (day surgery only)	
Brief description of how the service operates: SpaMedica Belfast is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with prescribed techniques or prescribed technology: establishments providing laser eye surgery using Class 3B or Class 4 lasers PT (L); private doctor (PD) and acute hospitals (day surgery only) AH (DS) categories of care. **Laser equipment available in the service:** Manufacturer: Nidek Model: YC-200 Nd-YAG Serial Number: Y2050351 Laser Class: Class 3B Wavelength: 635nm – 1064nm Manufacturer: Bausch + Lomb Model: Stellaris Elite Serial Number: SPC0556 Laser Class: Class 4 Wavelength: 532nm Manufacturer: Bausch + Lomb Model: Stellaris Elite Serial Number: SPC0557 Laser Class: Class 4 Wavelength: 523nm	

Types of treatment to be provided using the Nidek YC-200 laser:

- Cataract surgery
- YAG capsulotomy (anterior and posterior) for posterior capsule opacification
- YAG peripheral Iridotomy for cases of acute angle closure glaucoma

Types of treatment to be provided using the Stellaris Elite lasers:

- Vitreo-retinal (VR) procedures

It was confirmed that laser eye surgery is currently not provided by SpaMedica Belfast and that presently only two types of non-laser services are provided; cataract surgery and age-related macular degeneration (AMD) injections using the Nidek YC-200 laser.

The Stellaris Elite Lasers have not yet been placed into clinical service and a start date has not been set for this. This inspection included a review of the laser protection arrangements for the Nidek YC 200 YAG laser only

2.0 Inspection summary

This was an announced inspection undertaken by three care inspectors on 28 November 2024 from 10.00 am to 5.30 pm. RQIA's Laser Protection Advisor (LPA) accompanied the inspectors and reviewed the laser equipment and the laser safety arrangements. Their findings and recommendations are appended to this report.

The purpose of the inspection was to assess progress with areas for improvement identified during and since the last inspection and assess compliance with the legislation and minimum standards.

There was evidence of good practice concerning staff recruitment; authorised operator training; safeguarding; the management of the patients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the management of clinical records; clinical and organisational governance; and effective communication between patients and staff.

Additional areas of good practice identified included maintaining patient confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

As previously discussed laser eye surgery services have not yet commenced in SpaMedica Belfast and a start date had not been set. RQIA advised Mr Shepherd, responsible individual and Mrs Morrow, registered manager, that prior to laser eye surgical services becoming operational they must inform RQIA who will undertake a fresh review of the arrangements to provide laser eye surgery in the facility. An area for improvement had been made against the standards in this regard at the previous inspection. As laser eye surgical services have not yet commenced this area for improvement is carried forward for review at the next RQIA care inspection.

As a result of this inspection four areas for improvement were identified against the standards to: ensure there is a register of all personnel authorised to operate the Nidek YC 200 YAG laser; to ensure a named registered medical practitioner reviews the YAG Capsulotomy treatment protocol and this is clearly evidenced; to ensure authorised operators have up to date training in laser safety and their use that complies with current legislative requirements and professional guidelines, and to update the management of endophthalmitis procedure to reflect local arrangements should medical emergency occur in relation to endophthalmitis.

No immediate concerns were identified regarding the delivery of front line patient 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.

During the inspection a tour of the premises was undertaken and the inspectors met with Mr Shepherd and Mrs Morrow. Other SpaMedica Limited representatives were present and assisted with facilitating this inspection and included the hospital director North and Northern Ireland (NI), SpaMedica Ltd. For the purposes of this report those involved with facilitating the inspection will be referred to as the SpaMedica management team.

The information obtained is then considered before a determination is made on whether the clinic 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?

Clients were not present on the day of the inspection and client feedback was assessed by reviewing the most recent client satisfaction surveys completed by SpaMedica Belfast.

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

Two clients and one relative submitted responses. Client responses indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All clients indicated that they were very satisfied with each of these areas of their care. One client response included a comment that demonstrated they were highly satisfied with the care and treatment provided in SpaMedica Belfast.

Four staff submitted questionnaire responses. Staff responses indicated that they felt client care was safe, effective, that clients were treated with compassion and that the service was well led. All staff indicated that they were very satisfied with each of these areas of client care. A number of staff responses included comments stating that they were very happy working in the hospital where they felt supported and valued and where they received high quality training.

5.0 The inspection

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

Areas for improvement from the last inspection on 16 November 2023.		
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for improvement 1 **Ref:** Standard 48.21 **Stated:** First time	The responsible individual shall ensure the laser safety file contains an up to date copy of the laser protection advisor (LPA) risk assessment and completed action plan.	**Met**
	Action taken as confirmed during the inspection: The laser safety file contained an up to date copy of the laser protection advisor (LPA) risk assessment and completed action plan.	
Area for improvement 2 **Ref:** Standard 48.3 **Stated:** First time	The responsible individual shall the ensure the treatment protocol for vitreoretinal treatments (VR) surgery is reviewed to ensure its fit for purpose, reflects local practise and follows the headings stated in Standard 48.3.	**Met**
	Action taken as confirmed during the inspection: The treatment protocol for vitreoretinal treatments (VR) surgery had been reviewed to ensure its fit for purpose, reflects local practise and follows the headings stated in Standard 48.3. It is noted that VR surgery is not yet being provided.	
Area for improvement 3 **Ref:** Standard 48.3 **Stated:** First time	The responsible individual shall the ensure the treatment protocol for YAG Capsulotomy contains information on treatment contra-indications and a procedure if anything goes wrong with the treatment.	**Met**
	Action taken as confirmed during the inspection: The treatment protocol for YAG Capsulotomy contained information on treatment contra-indications and a procedure if anything goes wrong with the treatment.	

Area for improvement 4 **Ref:** Standard 48.3 **Stated:** First time **To be completed by:** 31 January 2024	The responsible individual shall ensure the Stellaris Elite laser register includes a field to record any accidents or adverse incidents.	**Met**
	Action taken as confirmed during the inspection: The Stellaris Elite laser register included a field to record any accidents or adverse incidents.	
Area for improvement 5 **Ref:** Standard 48.17 **Stated:** First time	The responsible individual shall ensure that, prior to placing the lasers into clinical service, the clinic should ensure that there is sufficient eyewear for the number of persons who will be present in the theatre during vitreoretinal treatments (VR) surgery laser treatments.	**Met**
	Action taken as confirmed during the inspection: There was sufficient eyewear for the number of persons who will be present in the theatre during vitreoretinal treatments (VR) surgery laser treatments.	
Area for improvement 6 **Ref:** Standard 48.21 **Stated:** First time	The responsible individual must contact RQIA prior to commencing laser eye surgery so that we have the opportunity to review relevant arrangements before the service is operational.	**Carried forward to the next inspection**
	Action required to ensure compliance with this standard was not reviewed as part of this inspection and this is carried forward to the next inspection. As stated previously the Stellaris Elite Lasers have not yet been placed into clinical service, and a start date has not been set for this. This area for improvement has been carried forward for review at the next RQIA inspection.	

5.2 Inspection outcome

5.2.1 How does this service ensure that staffing levels are safe to meet the needs of patients and staff are appropriately trained to fulfil the duties of their role?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of consultant ophthalmologists, optometrists, registered nurses and laser technicians who have evidence of specialist qualifications and skills in laser and non-laser eye surgery.

It was established that the laser eye surgery service has not yet commenced. RQIA advised Mr Shepherd and Mrs Morrow that, prior to laser eye surgical services becoming operational. SpaMedica Belfast must inform RQIA who will review the arrangements for the provision of the laser service and who the clinical authorised operators will be. As discussed, an area for improvement had been made against the standards in this regard during the previous inspection and has been carried forward for review at the next RQIA care inspection.

A review of records and discussion with staff and management demonstrated that clinic staff take part in ongoing training to update their knowledge and skills, relevant to their role. Induction programmes relevant to roles and responsibilities are required to be completed when new staff join the team. A review of records confirmed that the staff members, who had been appointed since the last inspection, had completed a formal and well-structured programme of induction.

An electronic system was in place to monitor all aspects of ongoing professional development and a record was retained of training and professional development activities for the majority of staff working in the establishment. A review of the records confirmed that in the main staff had undertaken training in keeping with RQIA training guidance and legislation.

All authorised operators should have up to date training in laser safety and their use that complies with current legislative requirements and professional guidelines. An area for improvement has been made against the standards in this regard. This area is discussed further in section 5.2.6.

It was identified that consultant ophthalmologists and optometrists are not line managed by Mrs Morrow and therefore Mrs Morrow does not have delegated responsibility for oversight of their training activities. Advice and guidance was provided to Mrs Morrow in this regard to ensure arrangements are in place that provide her with assurances that all persons working in SpaMedica Belfast have completed training in keeping with RQIA training guidance and legislation.

Discussion with Mrs Morrow in conjunction with a review of documentation confirmed that robust arrangements were in place to check the registration status for all clinical staff on appointment and twice yearly on an ongoing basis. The arrangements for monitoring the professional indemnity of all staff was also in place.

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

5.2.2 How does the service ensure that recruitment and selection procedures are safe?

The arrangements in respect of the recruitment and selection of staff were reviewed.

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

SpaMedica Limited has a corporate human resources (HR) shared services department. The corporate HR department supports Mrs Morrow during the recruitment process.

The HR department is responsible for shortlisting applications and developing job descriptions, induction templates and employment contracts bespoke to roles and responsibilities; and issuing reference requests.

The HR department is responsible for ensuring all recruitment records have been sought and uploaded to the electronic HR system. Mrs Morrow confirmed she has access to all recruitment records and is responsible for the interview and selection of staff on a local level. Discussions with Mrs Morrow confirmed that she had a clear understanding of recruitment and selection legislation and best practice guidance.

A review of a sample of two personnel files of staff recruited since the previous inspection confirmed that recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended had been sought and retained.

The staff register reviewed was found to be up to date and included the names and details of all staff who are and have been employed, in keeping with legislation.

It was determined that recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance.

5.2.3 How does the service ensure that it is equipped to manage a safeguarding issue should it arise?

Mrs Morrow stated that treatments are not provided to persons under the age of 18 years.

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 were included for onward referral to the local Health and Social Care Trust should a safeguarding issue arise.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Mrs Morrow confirmed that staff were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

It was confirmed that the safeguarding lead had completed safeguarding training at the level required in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards.

It was confirmed that a copy of the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) was available for reference.

Appropriate arrangements were in place to manage a safeguarding issue should it arise.

5.2.4 How does the service ensure that medical emergency procedures are safe?

The arrangements in respect of the management of medical emergencies were reviewed.

A review of the management of medical emergencies policy identified that it accurately reflected the arrangements that were in place for managing a medical emergency. Protocols were also available to guide the team on how to manage recognised medical emergencies.

The British National Formulary (BNF) and the Resuscitation Council (UK) specify the emergency medicines and medical emergency equipment that must be available to safely and effectively manage a medical emergency.

Review of the two emergency trollies found that robust systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date and are immediately available. In addition, there are two separate emergency boxes for intra-ocular pressure and endophthalmitis which are subject to regular monitoring. The management of endophthalmitis procedure was reviewed and it was noted that the arrangements outlined were not reflective of the local Northern Ireland arrangements. An area of improvement was identified against the standards to update the management of endophthalmitis procedure to reflect local arrangements should a medical emergency occur in relation to endophthalmitis.

Staff spoken with were able to describe the actions they would take, in the event of a medical emergency, and were familiar with the location of medical emergency medicines and equipment.

Discussion with staff confirmed that the management of medical emergencies is included in the induction programme. A review of training records evidenced that the nursing and medical staff had competed immediate life support training and all other staff had completed basic life support training.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency should one arise.

5.2.5 How does the service ensure that it adheres to infection prevention and control (IPC) and decontamination procedures?

The arrangements for IPC procedures throughout the clinic were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised. There were IPC policies and procedures in place that were in keeping with best practice guidance.

It was evidenced that a robust programme of IPC auditing is in place.

A tour of the premises was undertaken and the hospital was found to be clean, tidy and uncluttered. Cleaning records were completed and up to date.

Staff described the arrangements to decontaminate the environment and equipment between patients in keeping with best practice.

A review of training records confirmed that staff had received IPC training commensurate with their roles and responsibilities. Staff demonstrated good knowledge and understanding of IPC procedures.

The senior nurse informed us that reusable medical devices are used during cataract surgery. It was confirmed that arrangements were in place to ensure the decontamination of equipment and reusable medical devices is in line with manufacturer's instructions and current best practice. SpaMedica Belfast has a contract in place with the Central Sterile Services Department (CSSD) of the Ulster Hospital for this purpose.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance.

Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance.

The laser suite and treatment room provided dedicated hand washing facilities and hand sanitiser was available throughout the clinic.

SpaMedica Belfast is aware that the Department of Health (DOH) and Public Health Agency (PHA) websites provide advisory information, guidance and alerts with regards to IPC.

The service had appropriate arrangements in place in relation to IPC and decontamination.

5.2.6 How does the service ensure that laser procedures are safe?

It was confirmed that the lasers have not yet been placed into clinical service, and a start date has not been set for the Stellaris Elite Lasers. This inspection included a review of the laser protection arrangements for the Nidek YC 200 YAG laser only which is planned to be placed into clinical service.

RQIA's LPA supported the review the arrangements in respect of the safe use of the laser equipment and their findings are appended to this inspection report. These areas were discussed with Mrs Morrow and the SpaMedica management team who were advised that prior to placing the Nidek YC 200 YAG laser into clinical use the points identified in RQIA's LPA report should be actioned. These areas are included within this section of the report.

A review of the laser safety file found that it contained most of the relevant information in relation to all the laser equipment in place. However, there was no written confirmation of the appointment and duties of a certified LPA which should be reviewed on an annual basis. Following inspection, RQIA received evidence that this matter had been addressed. The following information should be added to the laser Safety File, written confirmation of appointment and duties of the Laser Protection Adviser and laser training records and certificates for all authorised operators and supporting staff.

The clinic's LPA had completed a risk assessment of the premises. It was noted that the digital copy of the risk assessment and action plan reflected that actions had been completed and signed off.

It was confirmed that laser eye procedures will be carried out by a consultant ophthalmologist acting as the clinical authorised operator who will be assisted by laser technicians acting as non-clinical authorised operators. A register of authorised operators was not in place. An area of improvement was identified against the standards to ensure there is a register of all personnel authorised to operate the laser in accordance with section 5 of the local rules and standard 48.2 of the Minimum Care Standards for Independent Healthcare Establishments.

The SpaMedica management team confirmed that a consultant ophthalmologist would undertake laser eye surgical procedures in accordance with treatment protocols. The YAG Capsulotomy treatment protocol was reviewed and it was noted it had been updated in 2024 by the Principal Optometrist and outlined all the required information. Two areas of improvement made on the previous inspection relating to the content of the treatment protocols had been met. However, in accordance with standard 48.4 of the Minimum Care Standards for Independent Healthcare Establishments, a named registered medical practitioner should review treatment protocols. An area of improvement has been identified against the standards to ensure a named registered medical practitioner reviews the YAG Capsulotomy treatment protocol and that this is clearly evidenced.

A system was in place to review the YAG Capsulotomy treatment protocol on an annual basis.

Local rules were in place which have been developed by the LPA and these contained the relevant information pertaining to the laser equipment being used. Arrangements were in place to review the local rules on an annual basis. The local rules included the following:

- the potential hazards associated with lasers
- controlled and safe access
- authorised operators' responsibilities
- methods of safe working
- safety checks
- personal protective equipment
- prevention of use by unauthorised persons
- adverse incident procedures

SpaMedica management team were advised to ensure all laser staff have signed to confirm that they have read and understood the latest version of the local rules.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of an appointed Laser Protection Supervisor (LPS) who is appropriately trained and experienced staff member who has direct involvement with the lasers. An LPS was identified for the laser.

Review of the authorised operator training records noted that there were no applications training records available. This was discussed with management who confirmed training is being arranged. An area for improvement has been identified against the standards to ensure authorised operators have up to date training in laser safety and their use that complies with current legislative requirements and professional guidelines. Authorised operators training records should be held in the laser safety file.

It was confirmed a laser register was in place and included sections for the following details of:

- the name of the person treated
- the date

- the operator
- the treatment given
- the precise exposure given
- any accidents or adverse incidents

It was confirmed that a previous area for improvement outlined in section 5.1 of this report relating to the content of the laser register has been met.

The laser suite and an identified treatment room where the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. Discussion with staff confirmed that the doors to the controlled areas are locked, when the laser equipment is in use, but can be opened from the outside in the event of an emergency.

The lasers are operated using an SD Card key or by entry of a PIN. It was confirmed that arrangements are in place to ensure the SD card key will be kept in the custody of the LPS and will only be issued to those on the approved list. The PIN will only be available to those on the approved list.

It was confirmed that protective eyewear was available for non-clinical authorised operators if required. A previous area of improvement relating to the adequate numbers of eyewear as outlined in the laser risk assessment was reviewed. A review of the eyewear evidenced that, eight pairs of eyewear for the Stellaris Elite lasers were mentioned in the risk assessment were in place. The previous area of improvement has been met. However, as stated previously, management confirmed there are no plans to place the Stellaris Elite lasers into clinical service.

The laser safety warning signs are illuminated and displayed outside of the laser suite and the laser treatment room when the lasers are in use and turned off when not in use, as described within the local rules. However, it was noted in relation to the laser controlled area for Optometrist Room 3, the hook used to hold the laser sign on the entrance door to the laser controlled area was missing. At the end of the inspection it was noted that the hook had been replaced.

Arrangements have been established for equipment to be serviced and maintained in line with the manufacturers' guidance. Copies of the service reports are in the laser safety files.

Carbon dioxide (CO2) fire extinguishers, suitable for electrical fires were available in the hospital and arrangements were in place to ensure the fire extinguishers are serviced, in keeping with manufacturer's instruction.

Addressing the areas for improvement as outlined will strengthen the governance and oversight arrangements concerning laser safety and will ensure laser procedures are provided in keeping with best practice guidance.

5.2.7 How does the clinic ensure patients have a planned programme of care and have sufficient information to consent to treatment?

The clinic has a list of fees available for each type of procedure offered. Fees for treatments are agreed during the initial consultation and may vary depending on the individual patient's prescription and surgery options available to them.

In accordance with General Medical Council (GMC) and the Royal College of Ophthalmologists guidance, patients meet with their surgeon on a separate day in advance of surgery, to discuss their individual treatment and any concerns they may have. They also meet the surgeon again on the day of surgery to complete the consent process for surgery.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment. Patients are also provided with clear post-operative instructions along with contact details if they experience any concerns. Systems were in place to refer patients directly to the consultant ophthalmologist if necessary.

Staff informed us that systems were in place to review the patient following surgery or procedures as per the clinical protocols.

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

It was determined that appropriate arrangements were in place to ensure patients have a planned programme of care and have sufficient information to consent to treatment.

5.2.8 Are there safe practices in place for the day surgery service?

We reviewed the arrangements for the provision of day surgery in the hospital outlined under their statement of purpose and categories of care. The review of day surgery arrangements evidenced that the service will operate in accordance with best practice and national standards to ensure care delivery is safe and effective.

The scheduling of patients for day surgery procedures will be co-ordinated by SpaMedica booking system with the involvement of senior nursing staff. Scheduling will take into account individual patient requirements, staffing levels, the nature of the procedure 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 patient will have a full assessment on admission. 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 theatre for cataract surgery or the treatment room for AMD injections.

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 completion of the surgical checklist and compliance will be routinely audited through the hospital's auditing process.

Patients receive local anaesthesia only. It was confirmed that patients will be observed during and after the procedure by appropriately trained staff. Patients are discharged in accordance to 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 will be provided with clear, post procedure advice information on follow up and who to contact in the event of a post treatment emergency.

A surgical register is maintained for all cataract surgery undertaken in the hospital and a separate register for AMD injections procedures.

Three patient care pathway records were reviewed relating to cataract surgery and AMD injection procedures. It was noted that the patient record is split between a hard copy record and an electronic record. Together they were found to provide a framework for the clear record of admission, medical history, IPC status, medication, observations on admission, pre-procedure checklist, surgical safety checklist (WHO), intra- procedure details, traceability details, post procedure observations and discharge record.

It was determined that appropriate arrangements were in place for the provision of day eye surgery.

5.2.9 Are robust arrangements in place regarding clinical and organisational governance?

Organisational governance
Various aspects of the organisational and medical governance systems were reviewed and evidenced clear organisational structure within SpaMedica Belfast. Mr Simon Shepard is the responsible individual in the clinic and Mrs Carly Morrow is the registered manager who is in day to day charge of the clinic.

Where the business entity operating a registered service 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.

A review of records confirmed that the most recent unannounced monitoring visit was undertaken 11 and 12 June 2024 by the clinical governance lead North, SpaMedica Limited. A report of the visit was produced and made available for patients, their representatives, staff, RQIA and any other interested parties to read and an action plan developed to address any issues identified during the visit which included timescales and person responsible for completing the action. It was noted that the previous unannounced quality monitoring visit report was dated June 2023. This was discussed with Mr Shepherd and the hospital director, North and NI, SpaMedica Ltd who informed us that they each undertake regular monitoring visits of SpaMedica Belfast throughout the year however, a report of these visits had not been generated. Mr Shepherd was very receptive to the advice provided and confirmed that unannounced quality monitoring visit reports will be generated on a six monthly basis with immediate effect.

The SpaMedica management team described an effective governance structure that provides a process and system of accountability to support the delivery of good quality service and to monitor and maintain high standards of care.

It was demonstrated that there was a clear management structure with defined lines of responsibility and accountability. Policies and standard operating procedures were in place to support practice on the organisation's intranet that was accessible to all staff.

There was a medical advisory committee (MAC) which meets quarterly with responsibility for surgeon performance and surgery specific matters. SpaMedica Limited monitors individual consultant files, checking registration with the GMC, professional indemnity and appraisals.

Discussion with staff and a review of records evidenced that staff meetings take place every month and minutes were available to review.

Staff working in different roles within the clinic confirmed that there were good working relationships and that management were responsive to any suggestions or concerns raised.

Clinical governance

As previously discussed, a team of consultant ophthalmologists, optometrists, registered nurses and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery work in the clinic.

One of the consultant ophthalmologists working in SpaMedica Belfast is considered to be wholly private doctor as they are not affiliated with the Health and Social Care (HSC) sector in NI and is not on the NI Primary Medical Performers List (PMPL). A review of this consultant's details confirmed evidence of the following was retained in keeping with best practice:

- 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 GMC
- ongoing annual appraisal by a trained Medical Appraiser
- an appointed responsible officer (RO)
- arrangements for revalidation

All medical practitioners working within the clinic must have a designated RO. 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. Experienced senior doctors (called RO's) 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.

The consultant ophthalmologists working within the clinic each have a designated external RO due to their prescribed connection with other health care organisations.

It was demonstrated that the consultant ophthalmologists had completed training in accordance with RQIAs training guidance for private doctors and are aware of their responsibilities under GMC Good Medical Practice.

Practising Privileges

As previously discussed, two consultant ophthalmologists who have specialist qualifications and skills in non-laser eye surgery work in the hospital.

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.

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.

A detailed policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place. It was advised that the policy is further developed to state that practicing privileges agreements should be reviewed at least every two years. SpaMedica management team were receptive this this advice.

A review of practising privileges records for the two identified consultant ophthalmologists confirmed that all required documents were in place. Mr Shepherd confirmed that all practising privileges agreements will be updated every two years.

Discussion with the SpaMedica management team demonstrated the oversight arrangements of the granting of practicing privileges agreements 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.

A clinical governance meeting is held bimonthly and is attended by representatives from the senior leadership team, hospital managers and clinical leads. Agenda items include clinical governance, quality, risk, compliance and audit. Significant incidents and themes reported are discussed at the organisation's national clinical governance and clinical effectiveness bimonthly meetings, medical advisory and health and safety committees.

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 SpaMedica Limited audit schedule. The results are monitored by the local, regional and national 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

Discussion with the SpaMedica management team and a review of records demonstrated that a robust system was in place to ensure that notifiable events were investigated and reported to RQIA and/or other relevant bodies as appropriate.

Mrs Morrow 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. An audit would be maintained, reviewed and the findings presented to the directors during their quarterly meetings.

Complaints Management

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

It was 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.

It was confirmed that no complaints had been received since the previous inspection. Mrs Morrow informed us any complaint received will be investigated and responded to appropriately to include details of all communications with complainants; the result of any investigation; the outcome and any action taken.

It was confirmed that any learning outcomes identified from the investigation of complaints received across the organisation will be used to improve the quality of services provided.

Overall, the governance structures within the clinic provided the required level of assurance to Mr Shepherd and the senior management team.

5.2.10 Does the service have suitable arrangements in place to record equality data?

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed with staff.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

6.0 Quality Improvement Plan/Areas for Improvement

Areas for improvement have been identified where action is required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)

	Regulations	Standards
Total number of Areas for Improvement	0	5*

*The total number of areas for improvement includes four that have been stated for the first time and one which is carried forward for review at the next inspection.

Areas for improvement and details of the QIP were discussed with Mr Shepherd, Responsible Individual and Mrs Morrow, Registered Manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

Quality Improvement Plan
Action required to ensure compliance with the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

Area for improvement 1 **Ref:** Standard 48.2 **Stated:** First time **To be completed by:** 28 January 2025	The responsible individual shall ensure there is a register of all personnel authorised to operate the Nidek YC 200 YAG laser in accordance with section 5 of the local rules and standard 48.2 of the Minimum Care Standards for Independent Healthcare Establishments. Ref: 5.2.6
	Response by registered person detailing the actions taken: There is now an authorised operator list held in the Laser Safety Folder for the Nidek YC 200 YAG Laser.
Area for improvement 2 **Ref:** Standard 48.4 **Stated:** First time **To be completed by:** 28 January 2025	The responsible individual shall ensure a named registered medical practitioner reviews the YAG Capsulotomy treatment protocol and this is clearly evidenced. Ref: 5.2.6
	Response by registered person detailing the actions taken: The YAG Capsulotomy treatment protocol has been reviewed and signed off by Mr Andre Oberholster GMC 4261010SP on 20/12/24. Signed copies available as evidence and printed and held in Nidek YAG Laser Safety Folder.
Area for improvement 3 **Ref:** Standard 48.12 **Stated:** First time **To be completed by:** 28 January 2025	The responsible individual shall ensure authorised operators have up to date training in laser safety and their use that complies with current legislative requirements and professional guidelines. Authorised operators training records should be held in the laser safety file. Ref: 5.2.6
	Response by registered person detailing the actions taken: The authorised operator for the Nidek YC 200 YAG (Mr Prateek Agarwal GMC 7745498) received safe use and application training on 17th December 2024 and the record of his training is held in the laser safety folder along with copies of core of knowledge training.
Area for improvement 4 **Ref:** Standard 18.1 **Stated:** First time **To be completed by:** 28 January 2025	The responsible individual shall update the management of endophthalmitis procedure to reflect local arrangements should a medical emergency occur in relation to endophthalmitis. Ref: 5.2.4
	Response by registered person detailing the actions taken: There is a separate standard operating procedure for handling pathology samples for suspected endopthalmitis relevant

	solely to Belfast, a copy of which is held in the endopthalmitis emergency box.
Area for improvement 5 **Ref:** Standard 48.21 **Stated:** First time **To be completed by:** 16 November 2023	The responsible individual must contact RQIA prior to commencing laser eye surgery so that we have the opportunity to review relevant arrangements before the service is operational. Ref: 5.2.7
	Response by registered person detailing the actions taken: The Responsible Individual will ensure that prior to vitreoretinal procedures commencing that the RQIA are contacted to review arrangements such as the authorised operator, local rules and risk assessments, safe use and application training and relevant pathways that are reviewed by a named registered medical practitioner on the specialist register.

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