

Announced Care Inspection Report 16 January 2017











Therapie Optilase

Type of service: Independent Hospital (IH) - Refractive Laser Eye Surgery, Cosmetic Laser Service and Private Doctor Address: Unit 0, Erneside Shopping Centre, Enniskillen, BT74 6JQ

Tel No: 08000121565 Inspector: Winnie Maguire

RQIA's Medical Physics Advisor: Dr lan Gillan

1.0 Summary

An announced inspection of Therapie Optilase took place on 16 January 2017 from 10.30 to 16.00.

Dr Ian Gillan, RQIA's Medical Physics Advisor accompanied the inspector to review the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

The inspection sought to assess progress with any issues raised during and since the previous inspection and to determine if the service was delivering safe, effective and compassionate care and if the service was well led.

Is care safe?

Observations made, review of documentation and discussion with Mr Mark Shortt, registered person, Ms Gemma Knightly, registered manager and staff demonstrated that generally systems and processes were in place to ensure that care to patients was safe and avoids and prevents harm. Areas reviewed included, staffing, recruitment and selection, safeguarding, laser safety, management of medical emergencies, infection prevention control and decontamination and the general environment. A requirement was made in relation to undertaking enhanced AccessNI checks for new staff prior to commencing employment and a recommendation was made to ensure the Soprano laser register is fully completed for each laser treatment provided.

Is care effective?

Observations made, review of documentation and discussion with Mr Shortt, Ms Knightly and staff demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included care pathway and communication. No requirements or recommendations have been made.

Is care compassionate?

Observations made, review of documentation and discussion with Mr Shortt, Ms Knightly and staff demonstrated that arrangements are in place to promote patients' dignity, respect and involvement in decision making. No requirements or recommendations have been made.

Is the service well led?

Information gathered during the inspection evidenced that there was effective leadership and governance arrangements in place which creates a culture focused on the needs of patients in order to deliver safe, effective and compassionate care. Areas reviewed included organisational and staff working arrangements, the arrangements for policy and risk assessment reviews, the arrangements for dealing with complaints, incidents and alerts, arrangements for practising privileges, insurance arrangements and the registered person's understanding of their role and responsibility in accordance with legislation. No requirements or recommendations have been made.

This inspection was underpinned by The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and The Department of Health, Social Services and Public Safety (DHSPPS) Minimum Care Standards for Independent Healthcare Establishments July 2014.

1.1 Inspection outcome

	Requirements	Recommendations
Total number of requirements and	1	1
recommendations made at this inspection	I	1

Details of the QIP within this report were discussed with Mr Mark Shortt, registered person and Ms Gemma Knightly, registered manager as part of the inspection process. The timescales for completion commence from the date of inspection.

Enforcement action did not result from the findings of this inspection.

1.2 Actions/enforcement taken following the most recent care inspection

Other than those actions detailed in the previous QIP there were no further actions required to be taken following the last inspection..

2.0 Service details

Registered organisation/registered person: Therapie Optilase (Enniskillen) Ltd Mr Mark Shortt	Registered manager: Ms Gemma Knightly
Person in charge of the establishment at the time of inspection: Mr Mark Shortt	Date manager registered: 17 November 2016

Categories of care:

(IH) Independent Hospital - PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers, PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources and PD private doctor

Laser Equipment

The laser services are provided in two distinct categories:

- Refractive laser eye surgery
- Dermatological laser service

Refractive Laser Eye Surgery

Laser Equipment

Manufacturer: Schwind A
Laser Class: Class 4
Model: Excimer laser

Serial Number: M573

Manufacturer: Abbott Medical Systems (AMO)

Laser Class: Class 3B

Model: Intralase IFS Advanced Femtosecond

Serial Number: 0814-80003

Laser Protection Advisor (LPA): Alex T Zarneh

Laser Protection Supervisor (LPS): Lawrence Dowie

Lisa McDowell

Clinical authorised users: Antonio Montanes (Consultant Ophthalmologist)

Non clinical authorised Users: Lawrence Dowie

Lisa McDowell Alex Nesbitt

Types of Treatment provided: Refractive laser eye surgery - Lasix and Lasex

Dermatological Laser Services

Laser Equipment

Manufacturer: Alma

Laser Class: Class 4 + infrared

Model: Soprano

Serial Numbers: two machines -S12ICE 0879

S12ICE0217 (off site for repair)

Laser protection advisor (LPA): Alex Zarneh

Laser protection supervisor (LPS): Gemma Knightly

Medical support services: Dr Ross Martin

Authorised users: Gemma Knightly

Catriona Garry Aimee Woods Amy McGourty Clare Monaghan

Types of Treatment Provided: Hair removal/reduction

3.0 Methods/processes

Questionnaires were provided to patients/clients and staff prior to the inspection by the establishment on behalf of the RQIA. Prior to inspection we analysed the following records: notifiable events, complaints declaration and returned completed staff and patient/client questionnaires.

During the inspection the inspector met with Mr Shortt, registered person, Ms Gemma Knightly, registered manager, a non-clinical authorised user (refractive laser eye service) and two authorised users (dermatological laser service). A tour of the premises was also undertaken.

Records were examined during the inspection in relation to the following areas:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- care pathway
- communication
- management and governance arrangements
- practising privileges
- maintenance arrangements

4.0 The inspection

4.1 Review of requirements and recommendations from the most recent inspection dated

The most recent inspection of the establishment was an unannounced care inspection. The completed QIP was returned and approved by the care inspector.

4.2 Review of requirements and recommendations from the last unannounced care inspection dated 9 March 2016 & announced care inspection dated 9 February 2016

Unannounced care in	spection - statutory requirements 9 March 2016	Validation of compliance
Requirement 1 Ref: Regulation 17(5) Stated: First time	The registered person must ensure that all incidents are recognised by staff, recorded, and reported in line with legislation, investigated and any learning disseminated to appropriate staff.	
	Action taken as confirmed during the inspection: No incidents have occurred since the previous inspection. Mr Shortt and Ms Knightly gave assurances that any future incidents would be managed in accordance with legislation.	Met
Requirement 2 Ref: Regulation 21	The registered person must ensure clients' records fully reflect all contacts with the client and information /advice given.	
Stated: First time	Action taken as confirmed during the inspection: Clients records reviewed fully outlined all contacts with clients.	Met
Requirement 3 Ref: Regulation 29 Stated: First time	The registered person must ensure that the absence of the registered manager is reported to RQIA in line with regulation 29 and the establishment's policy on the absence of the registered manager.	Met
	Action taken as confirmed during the inspection: The absence of the registered manager was reported to RQIA and a new registered manager is now in place.	
Requirement 4 Ref: Regulation 23 Stated: First time	The registered person must ensure that complaint's records relating to services delivered in the establishment are held in the individual establishment and learning disseminated to appropriate staff.	Met
	Action taken as confirmed during the inspection: Complaints records were available for inspection. Staff confirmed complaints are discussed at staff meetings.	

Unannounced care in	spection - recommendations- 9 March 2016	Validation of compliance
Recommendation 1 Ref: Standard 20	It is recommended the establishment is cleaned in accordance with the cleaning schedules and the cleaning schedules should only be signed when all cleaning has been completed.	
Stated: First time	Action taken as confirmed during the inspection: The establishment was found to be spotlessly clean and tidy. Robust cleaning schedules were in place and were fully completed by staff.	Met
Recommendation 2 Ref: Standard 7 Stated: First time	It is recommended all copies of the complaint's procedure made available to clients are up to date and accurately reflect the role of RQIA in the line with DHSSPS guidance on complaints. Action taken as confirmed during the inspection:	Met
	The client guide was found to be updated and included a complaints procedure.	

Last announced care 2016	inspection statutory requirements 9 February	Validation of compliance
Requirement 1 Ref: Regulation 25(2)d	The registered person must contact the establishment's LPA to clarify the use of the protective eyewear for the Schwind laser and amend local rules accordingly if necessary.	Met
Stated: First time	Action taken as confirmed during the inspection: Protective eyewear was in place and used as outlined in the local rules.	
Requirement 2 Ref: Regulation 25(2)d	The registered person must ensure all exit doors from the laser refractive eye suite have suitable locks and a laser warning sign in place at each exit when the lasers are in use.	
Stated: First time	Action taken as confirmed during the inspection: Following inspection Mr Shortt confirmed the LPA had amended the local rules to reflect that all exit doors from the laser refractive eye suite have suitable locks and a laser warning sign in place at each exit when the lasers are in use.	Met

Last announced care inspection recommendations - 9 February 2016		Validation of compliance
Recommendation 1	It is recommended that all areas identified for action in RQIAs LPA report are fully addressed.	
Ref: Standard 48	, ,	Mat
Stated: First time	Action taken as confirmed during the inspection: The areas identified have been addressed.	Met

4.3 Is care safe?

Staffing

Discussion with Mr Shortt, Ms Knightly and staff, confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and patients/clients. This includes a team of consultant ophthalmologists, a nurse and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery. The dermatological laser service is staffed separately by five authorised users.

Mr Shortt confirmed that refractive laser eye procedures are only carried out by trained medical practitioners acting as clinical authorised users and laser technicians acting as non-clinical authorised users. A register of clinical and non-clinical authorised users for the lasers is maintained and kept up to date in respect of the refractive laser eye surgery service. A register of authorised users is also maintained for the dermatological laser service.

A review of completed induction programmes evidenced that induction training is provided to new staff on commencement of employment.

A review of training records evidenced that all authorised users have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control and fire safety.

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, have received laser safety awareness training.

Evidence was available that confirms that staff who have professional registration, undertake continuing professional development (CPD) in accordance with their professional body's recommendations.

Discussion with Mr Shortt and review of documentation confirmed that there are systems in place for undertaking, recording and monitoring all aspects of staff supervision and ongoing professional development for staff. Staff appraisal had been undertaken in respect of some staff and Ms Knightly confirmed staff appraisal for all other staff has been arranged in the coming weeks.

A review of a consultant ophthalmologist's details confirmed there was evidence of the following:

- confirmation of identity
- current General Medical Council (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
- · arrangements for revalidation

Recruitment and selection

A review of five personnel files of authorised users recruited since the previous inspection and discussion with Mr Shortt confirmed that new staff have been largely recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

Evidence that basic AccessNI checks had been undertaken was available in each file, however the check was not the required enhanced check and four checks were noted to have been received after commencement of employment. Mr Shortt and Ms Knightly gave assurances that the five staff who had basic AccessNI checks carried out would have enhanced AccessNI checks carried out immediately. A requirement was made that enhanced AccessNI checks must be undertaken and received prior to new staff commencing work.

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

Safeguarding

Staff spoken with were aware of some types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

Policies and procedures were in place for the safeguarding and protection of adults and children. The policy and procedure for adult safeguarding was amended immediately following inspection to be in accordance to the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015) and an electronic copy was then forwarded to RQIA .All staff signed to confirm they have read and understood the policy. A copy of the relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise was also available.

Mr Shortt confirmed he would fully implement the policy including the identification and training of a safeguarding champion for the organisation.

Laser Safety

Refractive laser eye surgery service

A laser safety file was in place which contained all of the relevant information in relation to laser equipment.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires in July 2017.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols approved by a consultant ophthalmologist.

Up to date local rules were in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser equipment being used.

The establishment's LPA completed a risk assessment of the premises in 28 November 2016 and no recommendations were made.

A list of clinical and non-clinical authorised users was maintained and authorised users have signed to state that they have read and understood the local rules.

When the laser equipment is in use for the refractive laser eye service, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised user to deputise for the LPS in their absence, who is suitably skilled to fulfil the role.

The environment in which the laser equipment is used was found to be safe and 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 surgery is being carried out.

Mr Shortt forwarded amended local rules immediately following inspection outlining the arrangements to ensure each door to the laser suite is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency and that a laser safety warning sign is displayed on each door when the laser equipment is in use and removed when not in use.

The laser equipment is operated using keys and passwords. Arrangements were in place for the safe custody of the laser keys when not in use and passwords are only known by authorised users.

Protective eyewear was available for laser technicians if required, as outlined in the local rules.

The establishment has a laser surgical register which is completed every time the equipment is operated and includes:

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

A review of the laser surgical register during the inspection found it to be comprehensively completed.

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. Mr Shortt confirmed that refractive laser eye surgery had not taken place on the premises for over six months however a laser technician visits monthly to carry out quality assurance checks on the laser equipment. The laser equipment had been serviced within the last year.

The refractive laser eye service is due to recommence in the coming months.

Dr Ian Gillan, RQIA's Medical Physics Advisor, reviewed the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

Dermatological laser service

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Ross Martin and reviewed on 3 May 2016. Systems are in place to review the medical treatment protocols on an annual basis.

Up to date local rules were in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser equipment being used.

The establishment's LPA completed a risk assessment of the premises in 28 November 2016 and no recommendations were made.

Authorised users have signed to state that they have read and understood the local rules and medical treatment protocols. When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The door to the treatment room is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using keys. Arrangements are in place for the safe custody of the laser keys when not in use. Protective eyewear is available for the client and operator as outlined in the local rules.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

The establishment has a laser register for each laser which is completed every time the equipment is operated and included most of the following:

- the name of the person treated
- the date
- the operator

- the treatment given
- the precise exposure
- anv accident or adverse incident

Review of the laser register noted that on a number of occasions details of the treatment provided was not recorded. A recommendation was made on this matter.

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service reports of 2 November 2016 were available for inspection.

Management of Medical Emergencies

A review of medical emergency arrangements evidenced that emergency medicines were provided in keeping with the British National Formulary (BNF), and that emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained. A robust system was in place to ensure that emergency medicines and equipment do not exceed their expiry date. There was an identified individual with responsibility for checking emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance.

Discussion with staff demonstrated that they have a good understanding of the actions to be taken in the event of a medical emergency and the location of medical emergency medicines and equipment.

The policy on resuscitation was in place and provided clear instructions on what to do in the event of a medical emergency.

Infection Prevention and Control and Decontamination Procedures

There were clear lines of accountability for infection prevention and control (IPC) in place.

A range of information was available for patients/clients and staff regarding hand washing techniques.

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. Staff confirmed single use equipment is used where possible. Theatre sterile packs are provided from an accredited organisation.

Staff have been provided with IPC training commensurate with their role.

Discussion with staff confirmed they had a good knowledge and understanding of IPC measures.

A range of IPC audits have been carried out including:

- environmental
- hand hygiene
- post treatment infection

The compliance rate was noted to be very high and an action plan was in place for areas of non-compliance.

There were a range of IPC policies and procedures in place which are held within an IPC manual.

A review of infection control and prevention arrangements indicated very good infection control practices are embedded in the establishment.

Environment

The premises were maintained to a good standard of maintenance and décor.

Detailed cleaning schedules were in place and completed records of cleaning were displayed in various areas. Carbon dioxide (CO2) fire extinguishers were available which had been serviced within the last year.

Arrangements are in place for maintaining the environment. A legionella risk assessment has been undertaken and water temperatures are monitored and recorded as recommended. A fire risk assessment had been undertaken and staff confirmed fire training and fire drills had been completed. Staff demonstrated that they were aware of the action to take in the event of a fire.

Patient/client and staff views

Six patients/clients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm. The following comment was provided:

 "On each appointment I have had all stages explained to me and feel very much safe and protected "

Five staff submitted questionnaire responses. All indicated that they felt that patients/clients are safe and protected from harm. Staff spoken with during the inspection concurred with this. The following comment was provided:

 "Here at Therapie we are trained to a very high standard and client care and safety is top priority."

Areas for improvement

Enhanced AccessNI checks must be undertaken and received prior to new staff commencing work.

The Soprano laser register should include details of the laser treatment provided.

Number of requirements	1	Number of recommendations	1
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4.4 Is care effective?

Care Pathway

Refractive laser eye surgery

Patients have an initial consultation with a qualified optometrist who discusses their treatment options and the cost of the surgery.

During the initial consultation, patients are asked to complete a health questionnaire. There are systems in place to contact the patient's general practitioner, with their consent, for further information if necessary.

The establishment has a list of fees available for each type of surgical procedure. 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.

It was confirmed that in accordance to GMC 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 provided with clear post-operative instructions along with contact details for a senior optometrist if they experience any concerns. There are systems in place for the senior optometrist to refer patients directly to a consultant ophthalmologist if necessary.

Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

Two patient care records were reviewed. The establishment retains hard copy care records which are supplemented with an electronic record system. The patient care records were well documented, contemporaneous and clearly outlined the patient journey. The care records reviewed contained the following.

- patient details
- medical history
- signed consent form
- initial consultation
- pre-operative notes
- intra-operative notes
- post-operative notes
- review/follow up notes

Dermatological laser service

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes. The establishment has a list of fees available for each laser procedure. Fees for treatments are agreed during the

initial consultation and may vary depending on the type of treatment provided and the individual requirements of the client.

During the initial consultation, clients are asked to complete a health questionnaire. There are systems in place to contact the client's general practitioner, with their consent, for further information if necessary.

Five client care records were reviewed. There was an accurate and up to date treatment record for every client which included:

- client details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

Records management

Systems were in place to audit the completion of clinical records and an action plan is developed to address any identified issues. The outcome of the audit is reviewed through the establishment's clinical governance structures.

Information was available for patients/clients on how to access their health records, under the Data Protection Act 1998.

Mr Shortt confirmed arrangements are in place to register with the Information Commissioner's Office (ICO).

A review of documentation confirmed that the establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records.

The establishment also has a policy statement in place for clinical record keeping in relation to patient treatment and care which complies with GMC guidance and Good Medical Practice.

Communication

As discussed, there was written information for patients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The establishment has a policy for advertising and marketing which is in line with legislation.

Staff confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Staff confirmed that there are good working relationships and there is an open and transparent culture within the establishment.

Patient/client and staff views

All of the six patients/clients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. The following comment was provided:

• "I had a problem with my teeth during treatment (due to a dental problem). Xxxx found a solution to this and made sure I was comfortable at all times."

Five submitted staff questionnaire responses indicated that they felt that patients/clients get the right care, at the right time and with the best outcome for them. Staff spoken with during the inspection concurred with this. No comments were provided.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0

4.5 Is care compassionate?

Dignity respect and involvement with decision making

Discussion with staff regarding the consultation and treatment or surgery confirmed that patients'/clients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient/client and the optometrist or authorised user. Laser surgery is provided within a designated laser suite.

Information is provided to the patient/client in verbal and written form at all consultations to allow the patient/client to make choices about their care and treatment and provide informed consent.

As outlined previously patients meet with the surgeon on a separate day in advance of surgery and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

Appropriate measures are in place to maintain patient/client confidentiality and observations made evidenced that care records were stored securely in locked filing cabinets and electronic records are password protected.

Separate patient and client satisfaction surveys are carried out by the establishment on an ongoing basis and the results of these are collated to provide a monthly summary report which is made available to patients/clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that patients/clients were satisfied with the quality of treatment, information and care received. Some comments from patients/clients included:

- "Very good service "
- "Reassured and treated very well during all my sessions, happy with the results"

- "Very nice staff "
- "Able to call the therapists if I had any questions"
- "Excellent"

Patient/client and staff views

All of the six patients/clients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care. The following comment was provided:

 "Xxxx has been very compassionate at all times with me and understanding when I have needed to change appointment times at short notice."

Five submitted staff questionnaire responses indicated that they felt that patients/clients are treated with dignity and respect and are involved in decision making affecting their care. Staff spoken with during the inspection concurred with this. No comments were provided.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
4.6 is the service well led?			

Management and governance

There was a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Staff confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Ms Knightly has overall responsibility for the day to day management of the service. It was confirmed Mr Shortt visits the establishment at least monthly.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on annual basis. Staff spoken with were aware of the policies and how to access them.

Discussion with Mr Shortt demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Discussion with Mr Shortt demonstrated an increased awareness of complaints management following last year's inspection. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints have been managed in accordance with best practice.

It was confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was 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.

Mr Shortt confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to patients/clients at appropriate intervals. A monthly audit is conducted and it was confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. The audit programme included the following:

- laser log completion
- laser goggles safety
- laser machine service records
- clinic policies/procedures
- cleaning schedules
- · staff personnel files, training and certificates
- complaints
- patient/client files
- comment card completion

Mr Shortt outlined the process for granting practising privileges and confirmed medical practitioners meet with him prior to privileges being granted.

A medical practitioner's personnel file reviewed confirmed that there was a written agreement between the medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties. There are systems in place to review practising privileges agreements every two years.

A policy and procedure was in place in place which outlined the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

Mr Shortt demonstrated an understanding of his role and responsibility in accordance with legislation. It was confirmed that the Statement of Purpose and Patient's and Client's Guide are kept under review, revised and updated when necessary and available on request.

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

Observation of insurance documentation confirmed that current insurance policies were in place.

Patient/client and staff views

All of the six patients/clients who submitted questionnaire responses indicated that they felt that the service is well managed. The following comment was provided:

"There have been no changes that have had an effect on my treatment"

Five submitted staff questionnaire responses indicated that they felt that the service is well led. Staff spoken with during the inspection concurred with this. No comments were provided.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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5.0 Quality improvement plan

Any issues identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Mr Mark Shortt, registered person and Ms Gemma Knightly, registered manager as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all requirements and recommendations contained within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of the refractive laser eye surgery and cosmetic laser service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the laser services the RQIA would apply standards current at the time of that application.

5.1 Statutory requirements

This section outlines the actions which must be taken so that the registered provider meets legislative requirements based on 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.

5.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The DHSSPS Minimum Care Standards for Independent Healthcare Establishments(July 2014). They promote current good practice and if adopted by the registered provider/manager may enhance service, quality and delivery.

5.3 Actions to be taken by the registered provider

The QIP should be completed and detail the actions taken to meet the legislative requirements and recommendations stated. The registered provider should confirm that these actions have been completed and return the completed QIP to independant.healthcare@rqia.org.uk for assessment by the inspector.

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the registered provider from their responsibility for maintaining compliance with the regulations and standards. It is expected that the requirements and recommendations outlined in this report will provide the registered provider with the necessary information to assist them to fulfil their responsibilities and enhance practice within the service.

Quality Improvement Plan		
Statutory requirements		
Requirement 1	The registered provider must ensure that enhanced AccessNI checks are undertaken and received prior to new staff commencing work.	
Ref: Regulation 19 (2) Schedule 2 as amended	Response by registered provider detailing the actions taken: Complete and ongoing for all new staff members.	
Stated: First time		
To be completed by: 16 January 2017		
Recommendations		
Recommendation 1	The Soprano laser register should include details of each laser treatment provided.	
Ref: Standard 48.9		
Stated: First time	Response by registered provider detailing the actions taken: Staff training on completion of registers revisited. Staff now fully aware of requirements. Completed.	
To be completed by: 16 January 2017		





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