

Announced Care Inspection Report 26 September 2016



Ink-Out Tattoo Removal

Type of Service: Independent Hospital- Cosmetic Laser/IPL Service
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Tel No: 028 9024 2167
Inspector: Carmel McKeegan

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

1.0 Summary

An announced inspection of Ink-Out Tattoo Removal took place on 26 September 2016 10.30 to 12.00. The inspector was accompanied by Dr Ian Gillan, RQIA Medical Physics Advisor; the findings of Dr Gillan is appended to this report.

The inspection sought to assess progress with any issues raised during and since the last care inspection and to determine if the laser 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 Paul Clarke, registered person, demonstrated that systems and processes were in place to ensure that care to patients was safe and avoids and prevents harm. Areas reviewed included laser safety, staffing, recruitment and selection, safeguarding, management of medical emergencies, infection prevention control and decontamination, and the general environment. One recommendation was made to develop an adults at risk of harm policy.

Is care effective?

Observations made, review of documentation and discussion with Mr Clarke demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included care pathway, audits and communication. One recommendation was made in relation to the maintenance of client care records.

Is care compassionate?

Observations made, review of documentation and discussion with Mr Clarke 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 clients 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, 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 2014.

1.1 Inspection outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	0	2

Details of the Quality Improvement Plan (QIP) within this report were discussed with Mr Clarke, registered person/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 QIP there were no further actions required to be taken following the most recent inspection on 14 August 2015.

2.0 Service details

Registered organisation/registered person: Mr Paul Clarke t/a Ink-Out Tattoo Removal	Registered manager: Mr Paul Clarke
Person in charge of the home at the time of inspection: Mr Paul Clarke	Date manager registered: 21 January 2016
Categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers.	

Laser equipment

Manufacturer: Ultrapulse
 Model: Ultrapulse Laser F12
 Serial Number: F12 145DO912
 Laser Class: Class 4
 Wavelength: 1064nm & 532nm

Laser protection advisor (LPA) – Estelle Walker (Onephoton)

Laser protection supervisor (LPS) – Mr Paul Clarke

Medical support services - Dr Paul Myers

Authorised user - Mr Paul Clarke

Types of treatment provided – Tattoo removal

3.0 Methods/processes

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of the RQIA. Mr Clarke is the sole authorised user and does not employ any staff in connection with the delivery of the laser service. Prior to inspection we analysed the following records: complaints declaration and returned completed client questionnaires.

During the inspection the inspector met with Mr Clarke, registered person/manager and authorised user. The laser treatment room was reviewed also.

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
- information provision
- care pathway
- management and governance arrangements
- maintenance arrangements

4.0 The inspection

4.1 Review of requirements and recommendations from the most recent inspection dated 14 August 2015

The most recent inspections of the establishment were announced pre-registration care and estates inspections which were both undertaken on 14 August 2015. The completed QIPs were returned and approved by the care and estates inspectors. Following this, on receipt of outstanding information required in relation to estates issues, registration was approved on the 21 January 2016.

4.2 Review of requirements and recommendations from the last care inspection dated 14 August 2015

Last care inspection statutory requirements		Validation of compliance
Requirement 1 Ref: Regulation 9 (a) (b) Stated: First time	A copy of the Statement of Purpose and Client Guide should be submitted to RQIA.	Met
	Action taken as confirmed during the inspection: The Statement of Purpose and Client Guide had been provided to RQIA and approved.	

<p>Requirement 2</p> <p>Ref: Regulation 23 (1)</p> <p>Stated: First time</p>	<p>A complaints policy and procedure along with systems for managing and recording complaints should be developed and implemented.</p> <p>Action taken as confirmed during the inspection: A complaints policy and procedure was available for inspection and was seen to be reflective of best practice.</p>	Met
<p>Requirement 3</p> <p>Ref: Regulation 18 (2)(a)</p> <p>Stated: First time</p>	<p>Evidence of training in Basic Life Support, Fire Safety Awareness and Infection Prevention and control should be submitted to RQIA.</p> <p>Action taken as confirmed during the inspection: Evidence of training in fire safety awareness and infection prevention and control was provided to RQIA following the previous inspection. Mr Clarke confirmed he had attended basic life support training but could not locate the relevant certificate. RQIA received an email with photographic confirmation that Mr Clarke had completed basic life support and AED training on 20 November 2015.</p>	Met
<p>Requirement 4</p> <p>Ref: Regulation 15(7)</p> <p>Stated: First time</p>	<p>Policies and procedures for infection prevention and control should be developed and implemented.</p> <p>Action taken as confirmed during the inspection: Review of documentation and discussion with Mr Clarke confirmed that infection control policies and procedures had been provided and implemented.</p>	Met
<p>Requirement 5</p> <p>Ref: Regulation 15(7)</p> <p>Stated: First time</p>	<p>Arrangements must be in place to ensure that equipment is decontaminated between client use, in line with the laser manufacturer's guidance. A decontamination record should be retained.</p> <p>Action taken as confirmed during the inspection: Review of documentation confirmed that a record was maintained which demonstrated that equipment is decontaminated between client use.</p>	Met

<p>Requirement 6</p> <p>Ref: Regulation 21 (3) Schedule 3 Part II (3)</p> <p>Stated: First time</p>	<p>A laser register must be established as outlined in the main body of the report and completed each time the laser is used.</p> <p>Action taken as confirmed during the inspection: Review of documentation and discussion with Mr Clarke demonstrated that a record was completed every time the laser was operated, this was seen to include; the name of the person treated, the date, the operator, the treatment given, the precise exposure and any accident or adverse incident, where appropriate.</p>	Met
<p>Requirement 7</p> <p>Ref: Regulation 39</p> <p>Stated: First time</p>	<p>A copy of the laser protection advisor's (LPA) certificate of competence must be retained by the establishment in the laser safety file. A copy must also be forwarded to RQIA.</p> <p>Action taken as confirmed during the inspection: Review of documentation confirmed the LPA's certificate of competence was retained within the laser safety file.</p>	Met
<p>Requirement 8</p> <p>Ref: Regulation 28</p> <p>Stated: First time</p>	<p>An incident policy and procedure must be developed that includes reporting arrangements to RQIA in line with the notifiable events guidance.</p> <p>Action taken as confirmed during the inspection: Review of documentation and discussion with Mr Clarke confirmed an accident policy and procedure was in place. Mr Clarke was also knowledgeable on the notification procedure to RQIA should a notifiable event occur.</p>	Met
Last care inspection recommendations		Validation of compliance
<p>Recommendation 1</p> <p>Ref: Standard 48.13</p> <p>Stated: First time</p>	<p>It is recommended that laser safety awareness training is provided for staff working in the premises who are not directly involved in the use the laser.</p> <p>Action taken as confirmed during the inspection: A record of training was retained which confirmed that all other staff working in the premises had been provided with laser safety awareness training. The training record had been signed and dated by the participants.</p>	Met

Recommendation 2 Ref: Standard 20.2 Stated: First time	It is recommended that cleaning schedules are developed and implemented.	Met
	Action taken as confirmed during the inspection: A cleaning schedule was in place and up to date.	
Recommendation 3 Ref: Standard 48.16 Stated: First time	It is recommended that the laser safety warning sign is displayed when the laser is in use and removed when not in use as described within the local rules.	Met
	Action taken as confirmed during the inspection: A laser safety sign was provided, Mr Clarke demonstrated how the sign would be displayed when the laser was in use and removed when not in use.	

4.3 Is care safe?

Staffing

Discussion with Mr Clarke confirmed that he continues to be the sole authorised user of the laser machine and provides laser treatments on a weekly basis from the clinic.

A register of authorised users for the laser was maintained and kept up to date.

A review of training records evidenced that the authorised user has up to date training in core of knowledge training, application training for the equipment in use, infection prevention and control and fire safety. As previously stated Mr Clarke provided verification following the inspection, that he had completed basic life support training. Mr Clarke confirmed he would develop and read and sign a policy on protection of adults at risk of harm.

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

Recruitment and selection

As outlined Mr Clarke is the sole authorised user and has no plans to appoint any additional staff. It was confirmed that should staff be recruited in the future robust systems and processes will be developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

Safeguarding

Mr Clarke was aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

A policy and procedure was not provided for the safeguarding and protection of adults. The 'Adult Safeguarding, Prevention and Protection in Partnership' guidance and details for onward referrals were forwarded to Mr Clarke following inspection. Mr Clarke agreed to develop a protection of adults at risk of harm which would include this information. Mr Clarke should sign and date the policy to verify knowledge in this area. A recommendation was made in this regard.

Laser safety

A laser safety file was in place which contained all of the relevant information in relation to laser equipment. Mr Clarke was advised to declutter the file and to ensure the most recent version of documents were easily located. Previous versions of documents which have expired can be transferred to an archive file.

There was written confirmation of the appointment and duties of a certified laser protection advisor (LPA) which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires on 31 January 2017.

Laser procedures are carried out by a trained operator in accordance with medical treatment protocols produced by Dr Paul Myers. Records available during the inspection did not clarify when the treatment protocols had been reviewed, on 30 September 2016 RQIA received a copy of an electronic mail from Dr Paul Myers confirming that he had reviewed the medical treatment protocols in February 2016 and that the protocols have been certified for a further 12 months. The electronic mail also confirmed that a system was in place to review the medical treatment protocols on an annual basis. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

Up to date local rules are 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 on 2 February 2016 and no recommendations were made.

The laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised users is maintained. The authorised user has signed to state that he has 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 a key. Arrangements are in place for the safe custody of the laser key 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.

As previously stated the establishment has a laser 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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service report of August 2016 was reviewed as part of the inspection process.

Management of emergencies

As discussed, the authorised user has up to date training in basic life support. Discussion with Mr Clarke confirmed he is aware what action to take in the event of a medical emergency.

There was a resuscitation policy in place.

Infection prevention and control and decontamination procedures

The treatment room was clean and clutter free. Discussion with Mr Clarke evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As discussed previously, Mr Clarke has up to date training in infection prevention and control.

Environment

The premises were maintained to a good standard of maintenance and décor. Cleaning schedules for the establishment were in place.

Observations made evidenced that a carbon dioxide (CO₂) fire extinguisher has been provided and will be serviced annually.

Client views

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

- 'Well cared for and well informed.'

Areas for improvement

An adults at risk of harm policy should be developed which is reflective of the 'Adult Safeguarding, Prevention and Protection in Partnership'. Mr Clarke should sign and date the policy to verify knowledge in this area.

Number of requirements	0	Number of recommendations	1
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4.4 Is care effective?

Care pathway

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.

Review of the process for maintaining client care records identified that some information of the clients care and treatment had been recorded in the laser register this was discussed with Mr Clarke. A recommendation was made that there is an accurate and up to date treatment record for every client which includes:

- 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)

Observations made evidenced that client records are securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Mr Clarke confirmed that patient information is not recorded or stored electronically therefore the establishment is not registered with the Information Commissioners Office (ICO). Mr Clarke is aware of his responsibility in this regard.

Communication

As discussed, there is written information for clients 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.

Client views

All of the four 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:

- ‘Very assuring’

Areas for improvement

An accurate and up to date treatment record should be maintained for every client.

Number of requirements	0	Number of recommendations	1
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4.5 Is care compassionate?

Dignity respect and involvement with decision making

Discussion with Mr Clarke regarding the consultation and treatment process, confirmed that clients are treated with dignity and respect. The consultation and treatment is provided in a private room with the client and authorised user present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely in a locked storage cabinet within a locked room.

Mr Clarke confirmed a client satisfaction surveys was in the process of being carried out and the results of which will be collated to provide a summary report that will be made available to clients and other interested parties. Mr Clarke confirmed that this will be an annual process and an action plan will be developed to inform and improve services provided, if appropriate.

Client views

All of the four 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 comments were provided:

- ‘Yes, enjoyed experience.’
- ‘Very well treated and informed.’

Areas for improvement

No areas for improvement were identified during the inspection.

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

Management and governance

Mr Clarke has overall responsibility for the day to day management of the service and as previously stated does not employ any staff in relation to the delivery of the laser service.

Mr Clarke is the only authorised user in this establishment. Policies and procedures were available outlining the arrangements associated with laser treatments. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on annual basis.

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

A copy of the complaints procedure was available in the establishment. Discussion with Mr Clarke demonstrated good awareness of complaints management. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The returned questionnaire indicated that no complaints have been received for the period 14 August 2015 to 31 March 2016.

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.

Discussion with Mr Clarke confirmed that arrangements were in place to monitor and review the effectiveness and quality of care delivered to clients at appropriate intervals.

A whistleblowing/raising concerns policy was available.

Mr Clarke demonstrated a clear understanding of his role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. It was confirmed that the statement of purpose 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.

Client views

All of the four clients who submitted questionnaire responses indicated that they felt that the service is well managed. The following comments were provided:

- 'Yes well run.'
- 'I have been fully informed about all aspects of the treatment, the aftercare and lots of advice.'

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 Clarke, registered person/manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered person/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 person/manager 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 IH-Cosmetic Laser. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises 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 person/s 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 person(s) 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 RQIA office 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	
Recommendations	
Recommendation 1 Ref: Standard 3 Stated: First time To be completed by: 26 November 2016	A protection of adults at risk of harm should be developed which is reflective of the 'Adult Safeguarding, Prevention and Protection in Partnership'. Mr Clarke should sign and date the policy to verify knowledge in this area. Response by registered provider detailing the actions taken: <i>I have downloaded and read "Adult Safeguarding: Prevention and Protection from health-ni.gov.uk"</i>
Recommendation 2 Ref: Standard 48.10 Stated: First time To be completed by: 27 September 2016	Mr Clarke should ensure that there is an accurate and up to date treatment record for every client which includes: <ul style="list-style-type: none"> • 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) Response by registered provider detailing the actions taken: <i>all the above have been updated and implemented</i>

Name of registered manager/person completing QIP	<i>PAUL CLARKE</i>		
Signature of registered manager/person completing QIP	<i>Paul Clarke</i>	Date completed	<i>24.11.16</i>
Name of registered provider approving QIP			
Signature of registered provider approving QIP		Date approved	
Name of RQIA inspector assessing response			
Signature of RQIA inspector assessing response		Date approved	



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