

Announced Care Inspection Report 17 October 2018











Ink Unleashed Tattoo and Body Piercing

Type of Service: Independent Hospital (IH) – Cosmetic Laser Service Address: 5 Circular Road, Coleraine, BT52 1PS

Tel No: 028 7035 3001 Inspector: Carmel McKeegan

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

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 service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



2.0 Profile of service

This is an Independent Hospital (IH) – Cosmetic Laser Service which provides laser tattoo removal.

Laser equipment:

Manufacturer: Ultrapulse
 Model: Defender 5
 Serial Number: L15011401
 Laser Class: Class 4

Laser protection advisor (LPA):

Ms Estelle Walker (One Photon Ltd)

Laser protection supervisor (LPS):

Mr Andrew McKeary

Medical support services:

Dr Paul Myers

Authorised operators:

- Mr Andrew McKeary
- Mr Terry Whyte

Types of treatment provided:

Tattoo removal

3.0 Service details

Organisation/Registered Person: Andrew McKeary t/a Ink Unleashed Tattoo and Body Piercing	Registered Manager: Mr Andrew McKeary
Person in charge at the time of inspection: Mr Andrew McKeary	Date manager registered: 17 May 2018

Categories of care:

Independent Hospital (IH)

PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers

4.0 Inspection summary

An announced inspection took place on 17 October 2018 from 10.30 to 12.15.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidence in all four domains. These included the arrangements for managing medical emergencies; clinical records; the environment; infection prevention and control; maintaining client confidentiality; ensuring the core values of privacy and dignity were upheld; authorised operator training and providing the relevant information to allow clients to make informed choices.

Five areas requiring improvement were identified. Two areas of improvement were made against the regulations; to ensure that the service level agreement between the establishment and the laser protection advisor (LPA) is renewed annually and to provide the Regulation and Quality Improvement Authority (RQIA) with a copy of the most recent service report for the laser machine. Three areas of improvement were made against the standards; one of which has been stated for a second time, to ensure information requested by RQIA is submitted within the specified timescales. One area was made in relation to the provision and maintenance of a laser register and the other to ensure the most recent patient consultation summary report is provided to RQIA.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and clients experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	2	3

Details of the quality improvement plan (QIP) were discussed with Mrs Ashley McKeary, establishment manager and Mr Terry Whyte, authorised operator, 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.

4.2 Action/enforcement taken following the most recent care inspection dated 25 September 2017

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent announced follow-up pre-registration care inspection on 25 September 2017.

5.0 How we inspect

Prior to the inspection a range of information relevant to the service was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- the returned QIP from the previous care inspection

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of RQIA. Returned questionnaires were analysed prior to the inspection. RQIA also invited staff to complete an electronic questionnaire prior to the inspection. No completed staff questionnaires were submitted to RQIA.

A poster informing clients that an inspection was being conducted was displayed.

During the inspection the inspector met with Mrs Ashley McKeary, establishment manager and Mr Terry Whyte, authorised operator. Mr Andrew McKeary, registered manager and authorised operator was treating clients and was available for consultation and Mrs McKeary facilitated the inspection on his behalf.

The following records were examined during the inspection:

- 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

Areas for improvement identified at the last care inspection were reviewed and assessment of compliance recorded as met, partially met, or not met.

The findings of the inspection were provided to Mrs McKeary, manager, at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 25 September 2017

The most recent inspection of the establishment was an announced follow-up pre-registration care inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 25 September 2017

Areas for improvement from the last care inspection		
Action required to ensure Care Regulations (Northe	e compliance with The Independent Health	Validation of compliance
Area for improvement 1 Ref: Regulation 39 (2) Stated: Second time	Mr McKeary shall make arrangements to ensure the authorised operators complete mandatory training in the following areas: • infection prevention and control • basic life support • fire safety • safeguarding adults at risk of harm Action taken as confirmed during the inspection: Review of records confirmed that the authorised operators had both completed the mandatory training as outlined above.	Met
Area for improvement 2 Ref: Regulation 15 (1) (b) Stated: Second time	Mr McKeary shall ensure that all the recommendations made by the LPA in the risk assessment dated 2 May 2017 are fully addressed. Action taken as confirmed during the inspection: Review of records and discussion with staff confirmed that the recommendations made in the LPA risk assessment dated 2 May 2017 have been addressed.	Met

Area for improvement 3	Mr McKeary should ensure that a referral is made to the Northern Ireland Adverse Incident	
Ref: Regulation 15 (2) (b)	Centre (NIAIC) to report that the laser does not have the required classification label,	
Stated: Second time	aperture label and does not have an interlock socket.	
	Mr McKeary should also seek advice and guidance for the appointed LPA in this regard.	
	Confirmation of this referral should be submitted to RQIA upon return of this Quality Improvement Plan (QIP)	Met
	Action taken as confirmed during the inspection:	
	Following the previous inspection RQIA	
	received confirmation that a referral had been made to NIAIC. It was subsequently	
	established that no further action was required by Mr McKeary.	
Area for improvement 4	Mr McKeary should establish service	
Ref: Regulation 15 (2) (b)	arrangements for the laser. Service records for the laser should be retained in the laser safety file and available for inspection.	
Stated: Second time	,	
	Action taken as confirmed during the inspection:	
	Review of records confirmed that the laser had been serviced on 15 October 2017. Mrs	
	McKeary confirmed that service arrangements	
	have been established however the engineer was unable to service the laser machine	Met
	before this inspection. Mrs McKeary stated that the laser machine will be serviced within	
	the next few weeks.	
	A copy of the service report should be	
	submitted to RQIA upon return of the QIP and a separate area of improvement against the	
	regulations has been made in this regard.	

•	e compliance with The Minimum Care nt Healthcare Establishments (July 2014)	Validation of compliance
•	Int Healthcare Establishments (July 2014) Mr McKeary should ensure priority is given to developing the following: a recruitment and selection policy safeguarding policy and procedures infection prevention and control policies and procedures and procedures an advertising policy an accident and incident policy A copy of the policies listed above should be submitted to RQIA upon return of this QIP. Policies should be signed by the registered person and include the date of implementation and planned review. Action taken as confirmed during the inspection: It was confirmed that policies were provided in relation to recruitment and selection, safeguarding adults at risk of harm, infection prevention and control and accidents and incidents. Leaflets and flyers advertising laser tattoo removal were available for clients however an advertising policy had not yet been developed. Advice and guidance was provided to Mrs	compliance
Area for improvement 2	McKeary in this regard and on 13 November 2018 RQIA received written confirmation that an advertising policy was in place. Mr McKeary should establish if Ink Unleashed	
Area for improvement 2 Ref: Standard 8.5 Stated: Second time	Tattoo and Body Piercing is required to register with the Information Commissioner's Office (ICO). The outcome should be provided to RQIA upon return of this QIP.	
	Action taken as confirmed during the inspection: Review of records confirmed that this area of improvement had been addressed and the establishment had been advised that they were not required to register. However in light of the General Data Protection Regulations (GDPR) that came into effect during May 2018, this area is discussed further in section 6.5.	Met

Area for improvement 3 Ref: Standard 19.1 Stated: Second time	Mr McKeary should review Appendix 1 of the Minimum Care Standards for Independent Healthcare Establishments (July 2014) to identify relevant policies that should be developed by the establishment. Once identified, policies should be developed to fully reflect legislative and best practice guidance.	
	Action taken as confirmed during the inspection: Review of records verified that progress has been made in the development of policies and procedures. Mrs McKeary displayed a willingness to provide all required documentation and will develop policies as the need arises.	Met
Area for improvement 4 Ref: Standard 8.5 Stated: First time	Mr McKeary should ensure that any information requested by RQIA, and specifically the completion of a QIP, is submitted to RQIA within the timescales specified.	
	Action taken as confirmed during the inspection: Following the previous inspection the QIP was not returned to RQIA within the specified timescales. This area of improvement has not been addressed and has been stated for a second time.	Not met

6.3 Inspection findings

6.4 Is care safe?

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

Staffing

Discussion with staff confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and clients.

Mrs McKeary and the authorised operator confirmed that laser treatments are only carried out by authorised operators. A register of authorised operators for the laser is maintained and kept up to date.

It was confirmed that should authorised operators be recruited in the future they will complete an induction programme and records will be retained.

A review of training records evidenced that authorised operators have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control, fire safety and safeguarding of adults at risk of harm in keeping with the RQIA training guidance.

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

Recruitment and selection

There have been no authorised operators recruited since the previous inspection. During discussion it was confirmed that should staff be recruited in the future robust systems and processes have been 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.

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

Safeguarding

It was confirmed that laser treatments are not provided to persons under the age of 18 years.

Mrs McKeary and the authorised operator were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified, including who the nominated safeguarding lead was.

Review of records demonstrated that all staff in the establishment had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. It was confirmed that the safeguarding lead has completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

Policies and procedures were in place for the safeguarding and protection of adults at risk of harm. The policy included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

It was confirmed that copies of the regional policy entitled Co-operating to Safeguard Children and Young People in Northern Ireland (August 2017) and the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) were both available for staff reference.

Laser safety

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 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 expired on 14 May 2018. Mrs McKeary stated that Mr McKeary had contacted the LPA to renew the service level agreement, however this had not yet been completed. An area of improvement has been made against the regulations in this regard.

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Myers on 15 July 2018. Systems are 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 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 on 2 May 2017 and all recommendations made by the LPA have been addressed.

The laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. Authorised operators 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 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.

At the previous inspection it was confirmed that the establishment had a register which was completed every time the laser was operated. However during discussion with the authorised operator it became apparent that completion of the laser register had been discontinued. The purpose of maintaining the register was outlined to the authorised operator and further advice and guidance was provided in this regard.

An area of improvement has been made against the standards to ensure that a laser register is provided and completed each time the laser is operated and should include:

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

Mrs McKeary confirmed that arrangements have been established to service and maintain the laser in line with the manufacturer's guidance. As previously discussed, the engineer was unable to service the laser machine before this inspection. Mrs McKeary stated that the laser machine will be serviced within the next few weeks. An area of improvement has been made against the regulations to submit a copy of the service report to RQIA upon return of the QIP.

Management of emergencies

As discussed, authorised operators have up to date training in basic life support. Discussion with staff confirmed they were 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 Mrs McKeary 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, authorised operators have 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 is available which has been serviced within the last year.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to staff recruitment, induction, training, supervision and appraisal, adult safeguarding, management of emergencies, infection prevention and control, risk management and the environment.

Areas for improvement

Ensure that the service level agreement between the establishment and the LPA is renewed on an annual basis. A copy of the up-to-date LPA service level agreement should be provided to RQIA upon return of this QIP.

A laser register should be in place which is completed each time the laser is operated in keeping with the Minimum Care Standards for Independent Healthcare Establishments July 2014.

The laser equipment should be serviced in line with manufacturer's instructions and a copy of the most recent service report should be submitted to RQIA upon return of the QIP.

	Regulations	Standards
Areas for improvement	2	1

6.5 Is care effective?

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

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.

Four client care records were reviewed. 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. Mrs McKeary confirmed that this policy is under review.

Discussion with Mrs McKeary and review of the management of records policy confirmed that patients have the right to apply for access to their clinical records in accordance with the GDPR that came into effect during May 2018 and where appropriate Information Commissioners Office (ICO) regulations and Freedom of Information legislation.

Mrs McKeary confirmed that following the previous inspection she had contacted the ICO and were informed that the establishment was not required to register. Discussion took place regarding the application of the new GDPR and Mrs McKeary readily agreed to re-check with the ICO if the establishment was required to register.

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.

As discussed an advertising policy had not been developed. Advice and guidance was provided to Mrs McKeary in this regard who confirmed that a policy will developed in this regard.

Areas of good practice

There were examples of good practice found in relation to the management of clinical records, the range and quality of audits, health promotion strategies and ensuring effective communication between clients and staff.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

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

Dignity respect and involvement with decision making

Discussion with the authorised operator 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 operator 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 filing cabinet.

Mrs McKeary has developed a client satisfaction questionnaire which has been distributed to a sample of clients following laser treatments. The establishment is in the process of analysing the results of completed client satisfaction questionnaires which will be collated to provide a summary report and made available to clients and other interested parties. A copy of the summary report should be provided to RQIA upon return of the QIP. An area of improvement has been made against the standards in this regard.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining client confidentiality ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

Areas for improvement

A copy of the most recent patient consultation summary report should be provided to RQIA upon return of the QIP.

	Regulations	Standards
Areas for improvement	0	1

6.7 Is the service well led?

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

Management and governance

Mr McKeary, registered manager and authorised operator has overall responsibility for the day to day management of the service and as previously stated employs one other authorised operator in relation to the delivery of the laser service.

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 Mrs McKeary demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Discussion with Mrs McKeary demonstrated good awareness of complaints management.

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 also in place to ensure that urgent communications, safety alerts and notices are reviewed.

Discussion with Mrs McKeary 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.

Mrs McKeary confirmed that Mr McKeary had a clear understanding of his role and responsibility in accordance with legislation. It was confirmed that the statement of purpose and client's guide are kept under review, revised and updated when necessary and are 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.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to governance arrangements, management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.8 Equality data

Equality data

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

6.9 Client and staff views

Three client questionnaire responses were submitted to RQIA. All three clients indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All of the clients also indicated that they were very satisfied with each of these areas of their care

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Mrs Ashley McKeary, manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified 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 establishment. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DOH) Minimum Care Standards for Healthcare Establishments (July 2014).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP via Web Portal for assessment by the inspector.

Quality Improvement Plan	
Action required to ensure (Northern Ireland) 2005	e compliance with The Independent Health Care Regulations
Area for improvement 1 Ref: Regulation 39	The registered person shall ensure that the service level agreement between the establishment and the Laser Protection Advisor (LPA) is renewed on an annual basis. A copy of the up-to-date LPA service level agreement should be provided to RQIA upon return of this QIP.
Stated: First time To be completed by:	Ref: 6.4
12 December 2018	Response by registered person detailing the actions taken: A copie of the up to date LPA has been posted to Carmel Mckeegan
Area for improvement 2 Ref: Regulation 15 (2)	The registered person shall ensure that the laser equipment is serviced in line with manufacturer's instructions.
(b) Stated: First time	A copy of the most recent service report for the laser machine is submitted to RQIA upon return of the QIP.
To be completed by:	Ref: 6.4
12 December 2018	Response by registered person detailing the actions taken: A copy of the resent service report has been posted to Carmel McKeegan
Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)	
Area for improvement 1 Ref: Standard 8.5	Mr McKeary should ensure that any information requested by RQIA, and specifically the completion of a QIP, is submitted to RQIA within the timescales specified.
Stated: Second time	Ref: 6.2

To be completed by: 12 December 2018	Response by registered person detailing the actions taken: report filled after awaiting renewal of some papers which have now been filed.
Area for improvement 2 Ref: Standard 48.9	The registered person should ensure that a laser register is provided and completed each time the laser machine is operated and include the following information;
Stated: First time To be completed by: 12 December 2018	 the name of the person treated the date the operator the treatment given the precise exposure any accident or adverse incident Ref: 6.4 Response by registered person detailing the actions taken: A book has been set up to record all of the above detail and is stored the the locked laser room.
Area for improvement 3 Ref: Standard 5.1 Stated: First time To be completed by: 12 December 2018	The registered person shall ensure that a copy of the most recent patient consultation summary report is provided to RQIA upon return of the QIP. Ref: 6.6 Response by registered person detailing the actions taken: All copies of most recent patient consultation summery report has been provided to RQIA

^{*}Please ensure this document is completed in full and returned via Web Portal*





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