

HEALTHCARE INSPECTORATE WALES

Care Standards Act 2000

**INSPECTION REPORT
Independent Healthcare**

**Toned Within
Oxford House Clinic
Oxford Road
Llandudno**

**DATE OF INSPECTION
9th & 29th April 2008**

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Healthcare Inspectorate Wales
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INSPECTION REPORT

Inspection Episode: April 2008 to March 2009

Healthcare Provision:	Toned Within
Contact telephone number:	
Opening Days/Hours	
Registered Provider:	Mrs A Carri
Responsible Individual	
Registered Manager:	Mrs S Owen
Number of places:	0
Category:	Independent Hospital providing a 'Listed Service'
Date of first registration:	23 rd October 2007
Date of publication of this report:	15 th September 2008
Date of previous published report:	N/A
Lead Inspector:	Ms P Price
Specialist Inspectors/Advisors/ Observer:	Mr M Warsop

GUIDELINES ON INSPECTION

INTRODUCTION

This report has been compiled following an inspection of the establishment undertaken by Healthcare Inspectorate for Wales (HIW) under the provisions of the Care Standards Act 2000 and associated Regulations.

The report contains information on the process of inspection and records its outcomes. The report is divided into nine distinct parts reflecting the broad areas of the National Minimum Standards. An overall conclusion of the establishment's compliance with Private and Voluntary Healthcare (Wales) Regulations 2002 is recorded.

The HIW's Inspectors are authorised to enter and inspect healthcare establishments at any time. At each inspection episode or period there are visit/s to the service in addition to a range of other activities such as, self- assessment and the use of questionnaires. HIW try to find the best way of capturing patients, their relative/representatives and staff employed within the service experiences.

At any other time throughout the year visits may also be made to the service to investigate complaints and in response to changes in the establishment. Inspection enables the HIW to satisfy itself that continued registration is justified. It ensures compliance with:

- Care Standards Act 2000 and associated Regulations whilst taking into account the National Minimum Standards
- The setting's own Statement of Purpose

Readers must be aware that the report is intended to reflect the findings of the particular inspection episode. Readers should not conclude that the circumstances of the service will be the same at all times; sometimes services improve and conversely sometimes they deteriorate. The National Minimum Standards are also very detailed and some are technical in nature and the HIW does not look in depth at all aspects of these standards on each visit.

The report clearly indicates the requirements that have been made by HIW. This includes those made by HIW since the last inspection report which have now been met, requirements which remain outstanding and any new requirements from this recent inspection.

The reader should note that requirements made in last year's report which are not listed as outstanding have been appropriately complied with.

If you have concerns about anything arising from the Inspector's findings, you may wish to discuss these with the HIW or with the registered person.

Healthcare Inspectorate Wales is required to make reports on registered facilities available to the public. The report is a public document and will be available on the Healthcare Inspectorate Wales web site: <http://www.hiw.org.uk/>

OVERALL VIEW OF THE HEALTHCARE SETTING

Toned Within is located on the first floor of the Oxford House Clinic. The setting is registered to use the Lumenis Vasculite Elite Combined Nd: Yag Laser & Intense Pulsed Light System (IPL) for the following treatments, Hair Removal, Treating Pigmented Lesions, Treating Vascular Lesions, Photo Rejuvenation, Acne Treatments and Tattoo Removal.

Policies and other documentation were examined. The treatment room and equipment was also viewed and examined. Parking is available outside the clinic on the main road.

The treatment room is clean, tidy and appropriately maintained and procedures, records and equipment were available. Staff records were available.

Patient records are kept separately and securely. Documentation and information relating to IPL treatment is detailed and given to all patients, pre and post treatment.

Policies and procedures were available, some policies required time-dating, no central index available. It was noted that the statement of purpose required an additional element and no patients guide is available. This was discussed with the manager during the visit.

The Inspection manager would like to thank the manager for her time and co-operation during the inspection.

METHODOLOGIES USED IN THIS INSPECTION

Examination of policy and procedure documents. Discussions and feedback with the manager throughout the inspection process.

A further site inspection and follow-up visit was undertaken on the 29th April 2008. The purpose of the site inspection was to view an alternative room for the location of the Photoderm Vasculite Plus machine.

It was proposed to re-locate the machine into the adjacent room, previously occupied for IPL treatment, but which had subsequently relocated to other premises within Llandudno.

The room had a range of fitted cupboards to the right side and it was proposed to remove a small shelf to the right and also a large desk. This would then leave sufficient space for the head of the treatment couch to be placed against the left side partition wall, with the IPL machine placed in the corner. Adequate electrical sockets were available to the machine position.

The door to the room was currently fitted with a suitable secure lock and it was proposed to drape a towel over the wash basin taps for safety whilst treatments were undertaken.

The Laser Protection Adviser (LPA), Peter Cole, was due to visit the site on the 19th May 2008, in order to appraise the new location and revise the Local Rules accordingly.

The contract for continuation of Laser Protection Advice had been for the current year and had been renewed

INFORMATION PROVISION (C1)

Inspector's findings:

A Statement of Purpose was available. However, it required the addition of an element of regulation 5 schedule 1 to contain all the relevant required information.

There was no Patients Guide available for the Inspector to view. The Inspection advised the Registered Provider that this needed to be put in place within the agreed time-scale.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
The registered person shall compile in relation to the establishment a statement on paper (in these Regulations referred to as " the statement of purpose") which shall consist of a statement as to the matters listed in Schedule1. Aspect Schedule 1(7) needs to be added to the statement of purpose.	29 th April 2008 (Completed)	Regulation 5 Schedule 1(7)

<p>The registered person shall produce a written guide to the establishment (in these Regulations referred to as “the patient guide”) which shall include:</p> <p>A summary of the statement of purpose;</p> <p>The terms and conditions in respect of services to be provided for patients, including as to the amount and method of payment of charges by patients for all aspects of their treatment;</p> <p>A standard form of contract for the provision of services and facilities by the registered provider to patients;</p> <p>A summary of the complaints procedure established under Regulation 22;</p> <p>A summary of the results of the most recent consultation conducted in accordance with Regulation 16(3);</p> <p>The address and telephone number of the appropriate office of the Welsh Assembly Government; and</p> <p>The most recent inspection report prepared by the Welsh Assembly Government or information as to how a copy of that report may be obtained.</p>	<p>29th April 2008 (Completed)</p>	<p>Regulation 6(1)</p>
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Good Practice Recommendations:
It is advised that the statement of purpose and the patients guide be held in separate folders. This will make it easier for potential patients to access.

QUALITY OF TREATMENT AND CARE (C2 – C7)

Inspector's findings:

Pre and post treatment information is available and given to patients. Treatment provided to patients is in line with appropriate guidelines with regard to IPL treatment.

All patients will receive questionnaires with regard to the quality of their treatment and care and outcomes will be noted and acted upon. Annual audit of results will be collated and will be made available in the patients guide, when this is made available.

Policies and procedures are in place, however it was noted that a number of policies will require to be time-dated. It is advised that a central index sheet be made available. It was also noted that reference was made to Care Standards. This requires amending to National Minimum Standards (NMS).

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
The registered person shall produce a written guide to the establishment (in these Regulations referred to as "the patient guide") which shall include: A summary of the results of the most recent consultation conducted in accordance with Regulation 16(3);	29 th April 2008 (Completed)	Regulation 16(1)
	30 th May 2008 and ongoing.	Regulation 16(3)

Good Practice Recommendations:

It is advised that a central index sheet be made available.

Reference was made to Care Standards. This requires amending to National Minimum Standards (NMS).

MANAGEMENT AND PERSONNEL (C8 – C15)

Inspector's findings:

The registered manager and provider has undertaken appropriate courses and has the qualifications and experience required for undertaking, and supervising this treatment.

Human resources policies and procedures are in place. Criminal Bureau Checks (CRB) are undertaken.

The clinic does not treat children under the age of eighteen.

A Protection of Vulnerable Adults (POVA) file was unavailable. The local social services need to be contacted to supply the file. Protection of Vulnerable Adults training has been undertaken.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

A Protection of Vulnerable Adults (POVA) file needs to be accessed from local social services.

COMPLAINTS MANAGEMENT (C16 – C18)

Inspector's findings:

A complaints policy and procedure is available. However, the time-scales require reviewing in line with National Minimum Standards (NMS)

The complaints policy and procedure clearly outlines the process for patients in how to make a complaint.

A whistle blowing policy and procedure in place.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
Complaints process must be amended in line with National Minimum Standards (NMS)	29 th April 2008 (Completed)	Regulation 22(1)

Good Practice Recommendations:

None

PREMISES, FACILITIES AND EQUIPMENT (C19 – C21)

<p>Inspector's findings:</p> <p>The Intense Pulsed light machine was located within the last room on the left-hand side of the first floor accommodation. This room is referred to as the 'controlled area' for registration purposes.</p> <p>The room was clean, maintained to an acceptable standard and appropriate for the treatments carried out.</p> <p>The room was furnished with a treatment couch, wash basin and the Phototherm Vasculite Plus machine. Other equipment was present in respect of treatments that were not registerable, including a small class 3B laser, where treatments were carried out by a qualified healthcare professional in accordance with Regulation 2(b)</p> <p>It was recommended that black-out blinds be fitted to the windows.</p> <p>Testing of the electrical wiring installation, fire alarms, emergency lighting and fire extinguishers have been carried out at appropriate intervals by the landlord of the building and records were available for inspection.</p> <p>A fire policy for the building was available, but little information on fire training and fire drills. This needed to be addressed.</p>
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Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
Implement fire training and fire drills for all staff on at least two occasions a year.	1 st June 2008	Regulation 24(4)(c)&(d)

Good Practice Recommendations:

To fit black-out blinds to the windows.

RISK MANAGEMENT (C22 – C30)

Inspector's findings:

Risk management policy and procedure in place. The registered manager reviews and undertakes, risk assessments.

Portable electrical appliances within the IPL area had been tested on 16th May 2007.

Policy and procedures in place and Health and Safety issues are covered in the staff /training process. Health & Safety update training undertaken in April 2008.

A policy and procedure is available in relation to Infection Control. Staff members are aware of the importance of infection control procedures.

First aid training update undertaken in April 2008.

The registered manager is responsible for monitoring and reviewing the quality of goods and services provided at the clinic.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

None

RECORDS AND INFORMATION MANAGEMENT (C31 – C33)

Inspector's findings:

Policy and procedures in place. Individual patient records are maintained and stored separately and securely. Only the registered manager has access to the key.

The patient's health history is taken during the consultation session. All records are maintained of all episodes of treatment and responses.

All patients sign a detailed consent form prior to treatment. However, it was noted that patients had not signed the pre-assessment/medical history form. The manager was advised that patients should sign this form.

The Clinic complies with the Data Protection Act.

All personnel are made aware of the need for patient confidentiality as it is covered during induction.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

Patients should sign the pre-assessment/medical history form.

RESEARCH (C34)

Inspector's findings:
No research is carried out at this establishment

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

None

Prescribed Techniques and Technologies
(Standards P1 to P3)

CLASS 3B AND 4 LASERS AND/OR INTENSE PULSED LIGHT SOURCES

STANDARD P1 : Procedures for Use of Lasers and Intense Pulsed Lights

Inspector's findings:

The clinic had medical protocols in place, which had been prepared by Dr. Ross Martin of GCG Healthcare, and had been signed and dated 21st July 2006. These were noted as being valid until 21st July 2009.

Dr. Ross Martin was currently registered with the General Medical Council.

It was noted that the protocols had been written for a Vasculite Elite, which was not exactly the machine present on the premises. It was subsequently advised by Peter Cole of Cole Scientific Consultancy Ltd, that the protocols had been drawn up for a combined machine, but with a dummy head fitted and the machine would only act as an IPL in accordance with the Local Rules.

The Local Rules had been prepared by Steven Hill as the Laser Protection Advisor, but he had since retired in February 2007.

Subsequently, this role had been taken over by Peter Cole with effect from 26th March 2007, and he was contracted to provide laser support for a twelve month period.

This had recently expired but arrangements had been made for Peter Cole to continue in this capacity and he was due to visit the clinic again on 19th May 2008. In a professional capacity he is RPA 2000 registered.

The laser protection supervisor for the premises continued to be Andrea Carri and she was the person responsible for safety within the controlled area.

A register of authorised users was available and this was limited to Andrea Carri and Susan Owen.

The treatment register was completed each time a treatment was carried out.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

None

STANDARD P2 : Training for Staff using Lasers and Intense Pulsed Lights

Inspector's findings:

The Laser Protection Supervisor, Andrea Carr and assistant Sue Owen had undertaken specific vasculite training on the operation of the IPL machine in May 2006.

They had both subsequently undertaken core of knowledge training with Cole Scientific on 26th March 2007 and certificates had been provided.

In respect of continuing professional development (CPD), currently this was mainly sourced by keeping abreast of developments within beauty journals etc.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

None

STANDARD P3 : Safe Operation of Lasers and Intense Pulsed Lights

Inspector's findings:

The room used for IPL is clearly defined as the controlled area and on occasions is used for other purposes. The controlled area is not used as access to any other areas.

The equipment was a Photoderm Vasculite Plus machine, serial number SA 230100 140 990003. The machine was appropriately labeled with the operating wavelength and maximum power outputs.

An appropriate CO₂ fire extinguisher was located in the corridor immediately outside of the controlled area.

Appropriate warning signs were affixed to the outside face of the controlled area door, and the door was secured whilst treatments were being carried out.

The protective eye-wear provided by the clinic is satisfactory in terms of markings and providing the correct level of protection for the operator of the IPL and the patient.

There were three sets of protective eyewear available, CE03, CE04 and CE05 and these should only be employed in accordance with the requirements of the Local Rules.

The key for the machine was kept in a container placed within a locked cabinet within a locked room. As there is more than one operator listed, it is recommended that the key be signed out and signed back in after treatments.

The machine had been serviced by Medi-Lase Ltd on 10th March 2008, but there was currently a fault with the mechanism for switching on the machine and a spare part, recently delivered, was due to be fitted.

It was not possible therefore to record the number of shots for the machine.

Requirements made since the last inspection report which have been met:

Action Required	When Completed	Regulation Number
None		

Requirements which remain outstanding from previous inspection activity:

Action Required	To have been completed by	Regulation Number
None		

New requirements from this inspection:

Action Required	Timescale for completion	Regulation Number
None		

Good Practice Recommendations:

It is advised that current shot usage from the IPL machines should be entered in the appropriate book after each patient treatment. This will assist in maintaining a true record of machine usage.

Inspector's Name: P Price

Date: 15th September 2008

Inspector's Signature:

