



Independent Healthcare Inspection (Announced)

Rethink the ink

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1. Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW inspections of independent healthcare services seek to ensure services comply with the Care Standards Act 2000 and requirements of the Independent Health Care (Wales) Regulations 2011 and establish how services meet the National Minimum Standards (NMS) for Independent Health Care Services in Wales¹.

This report details our findings following the inspection of an independent health care service. HIW is responsible for the registration and inspection of independent healthcare services in Wales. This includes independent hospitals, independent clinics and independent medical agencies.

We publish our findings within our inspection reports under three themes:

- Quality of patient experience
- Delivery of safe and effective care
- Quality of management and leadership.

¹ The National Minimum Standards (NMS) for Independent Health Care Services in Wales were published in April 2011. The intention of the NMS is to ensure patients and people who choose private healthcare are assured of safe, quality services. <http://www.hiw.org.uk/regulate-healthcare-1>

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Interviews with staff (where appropriate) and registered manager of the service
- Conversations with patients and relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of equipment and the environment
- Information within the service's statement of purpose, patient's guide and website (where applicable)
- HIW patient questionnaires completed prior to inspection.

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Any urgent concerns that may arise from an inspection will be notified to the registered provider of the service via a non-compliance notice². Any such findings will be detailed, along with any other improvements needed, within Appendix A of the inspection report.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

² As part of HIW's non-compliance and enforcement process for independent healthcare, a non-compliance notice will be issued where regulatory non-compliance is more serious and relates to poor outcomes and systemic failing. This is where there are poor outcomes for people (adults or children) using the service, and where failures lead to people's rights being compromised. A copy of HIW's compliance process is available upon request.

3. Context

Rethink the ink is registered as an independent hospital because it provides Class 3B/4 laser and treatments at 9-15 New Road, Porthcawl. The service was registered in March 2015.

At the time of inspection, the registered manager was the only member of staff operating the laser. The service is currently registered to provide the following treatments to patients over the age of 13 years:

Q Medicx, Q-Switched Nd: YAG laser for the following treatment:

- Tattoo removal
- Birthmarks
- Fletches.

Star IPL, Q-Switched Nd: YAG laser for the following treatment:

- Tattoo removal
- Birthmarks
- Fletches.

4. Summary

We identified areas for improvement and regulatory breaches during this inspection. Further details of these improvements are provided in Appendix A.

This is what we found the service did well:

- Patients were provided with enough information to make an informed decision about their treatment
- The service is committed to providing a positive experience for patients
- We saw evidence that patients were satisfied with their treatment and the service provided.

This is what we found the service needed to improve:

- Updates to the patient's guide and statement of purpose
- Arrangements for the safety of the environment and laser/IPL equipment
- Arrangements for safeguarding vulnerable adults and children
- Arrangements for managing risk and health and safety, including precautions around fire
- Updates to policies and procedures
- Systems for governance and monitoring the quality of the service against the requirements of the regulations and standards.

Given the findings from this inspection, improvements are needed in the quality assurance and governance arrangements of this service to ensure compliance with the relevant regulations and standards. This is important to ensure the safety and effectiveness of the service provided.

Whilst this has not resulted in the issue of a non compliance notice, there is an expectation that the registered manager and responsible individual take meaningful action to address these matters, as a failure to do so could result in HIW taking action for non-compliance with the regulations.

5. Findings

Quality of patient experience

Patient information and consent (Standard 9)

We found evidence to indicate that patients were provided with enough information to make an informed decision about their treatment.

We were told that patients were provided with a verbal consultation prior to treatment, which included discussion of the risks and benefits. Patients were asked to provide written consent to treatment and we saw examples of information and aftercare guidance given to patients. We saw also that patients were asked to complete medical history forms.

A treatment register was maintained in addition to individual patient notes. However, the following areas needed to be addressed in order to provide a comprehensive record of each treatment:

- Only the patients first name was recorded in the treatment register rather than their full name or a unique patient identifier
- Records of the area of the patient treated were needed further detail, for example 'arm' was stated rather than 'upper left arm'
- Not all relevant laser parameters were recorded, such as wavelength (nm), energy (J), frequency (Hz) and shot count
- Space was not available to record details of any adverse effects following treatment
- Individual treatment notes needed further details about each patient's treatment, such as why changes to treatment were made.

Improvement needed

Improvements must be made to the treatment register to ensure that comprehensive records of treatment are maintained.

Communicating effectively (Standard 18)

A patient's guide document was available but needed to be updated to include a summary of the latest patient feedback.

Improvement needed

The patient's guide must be updated in accordance with the regulations.

We found that a statement of purpose was available, but updates were needed to comply with the regulations, including:

- The email address of the registered manager
- Updates to the types of lasers in use, including make and model as referenced in the local rules
- References to home visits to patients should be removed, as this is not provided by the service
- Further details about the arrangements for chaperones, including whether chaperones can be present during treatment
- Clarification on how patient feedback is obtained.

Improvement needed

The statement of purpose must be updated in accordance with the regulations.

A copy of the updated statement of purpose must be sent to HIW.

Citizen engagement and feedback (Standard 5)

Before the inspection, the clinic was asked to give out HIW questionnaires to obtain patient views of the services provided. Six patient questionnaires were completed prior to the date of inspection. The questionnaires completed showed that all patients strongly agreed with statements that the clinic was clean, tidy and that staff were polite, caring, listened and provided enough information about their treatment. Patients rated the care and treatment provided as 'excellent'.

The registered manager told us that patients were able to provide feedback on the service's Facebook page. However, there was no formalised system for obtaining patient feedback as a way of monitoring the quality of the care provided, such as by conducting questionnaires. We also advised that patients should be able to provide this feedback anonymously.

Improvement needed

There must be a system in place for regularly seeking patient feedback.

Delivery of safe and effective care

Safe and clinically effective care (Standard 7) and medical devices, equipment and diagnostic systems (Standard 16)

We saw certificates to show that the registered manager had completed training in the use of the laser machine and Core of Knowledge³.

There were local rules in place, which detail the safe operation of the equipment and were signed by the registered manager to indicate their agreement to follow them. The registered manager informed us that they had recently sold one of the laser machines, meaning that a review of the local rules is needed to reflect the changes to equipment.

Improvement needed

The local rules should be reviewed to reflect the changes in the equipment in use.

We saw that eye protection was available for patients and the laser operator. The eye protection appeared in visibly suitable condition. We saw evidence that the suitability of eye protection had been considered by the Laser Protection Adviser.

We were told that the laser machine in use was relatively new and due to this had not been serviced. We discussed with the registered manager the importance of on-going servicing and maintenance of the machine to ensure it was in a safe and suitable condition for use.

Improvement needed

There must be suitable arrangements in place to ensure the laser machine equipment is safe, maintained in good condition and can be regularly serviced, as and when this is required.

We were concerned that the environmental risk assessment of the treatment/controlled area was not sufficient. This is because we found that due to the positioning of the laser during treatment the window blind may not be sufficient to

³ Core of Knowledge training is intended for operators using lasers and IPL systems for various skin treatments. The training includes information and guidance on the safe use of lasers and IPL systems.

stop stray laser radiation from escaping the controlled area and potentially causing a hazard for others outside the room. Furthermore, although we saw that a contract was in place with a Laser Protection Adviser, it was not clear from the documentation when the Laser Protection Adviser had last visited the premises and whether this had occurred following changes to the equipment. Therefore, we could not be assured that the safety of the environment had been sufficiently assessed to ensure the safety and welfare of patients treated and others.

During the inspection we were told that children had been occasionally admitted to the controlled area to accompany their parents during treatment. Although they were provided with eye protection, due to the risks to their safety and welfare and children should not be allowed into the controlled area, unless receiving treatment.

We highlighted these issues around the safety of the environment and presence of children to the registered manager on the day of inspection so that this could be addressed immediately prior to further patient treatment. We also issued a letter following the inspection, where the service was required to take urgent action to address our findings. Further details of this are available in Appendix A.

There was a warning sign outside the treatment room to indicate the presence of a laser machine. There was also a warning light that could be switched on when the laser was in use. The registered manager confirmed that the treatment room doors were locked when in use, in order to prevent unauthorised access. However, we saw that improvements were needed to the security of the activation keys for the machines as these had not been removed when the machine was not in use, to prevent unauthorised use.

Improvement needed

The registered manager should take steps to prevent unauthorised use of the IPL/laser machines, specifically by ensuring the activation keys are stored securely.

Safeguarding children and vulnerable adults (Standard 11)

The service is registered to treat patients over the age of 13 years.

We found that improvements were needed to adequately safeguard patients, including the following:

- A child and vulnerable adult protection policy was not in place to ensure there is a clear procedure to follow in the event of a safeguarding concern
- Clear procedures for assessing mental capacity to consent to treatment were needed

- The registered manager had not completed up-to-date training in safeguarding
- Clear procedures on consent arrangements and the treatment of children were not in place, including the arrangements for chaperones and the presence of a parent/guardian.

Improvement needed

Robust processes must be in place to ensure that children and vulnerable adults who may use the service are adequately safeguarded. Specifically, clear policies and procedures on safeguarding, consent and the treatment of children must be created; safeguarding training should be conducted.

Infection prevention and control and decontamination (Standard 13)

We saw the service was visibly clean and tidy. An infection control policy was in place, but we found this needed to be updated to include further details of the arrangements for cleaning at the service.

Improvement needed

The infection control policy must be updated with further details of the cleaning arrangements.

Managing risk and health and safety (Standard 22)

We looked at the maintenance arrangements in place. We saw evidence that Portable Appliance Testing (PAT) testing had been recently conducted, to help ensure that small electrical appliances were safe to use. We also saw evidence of a five yearly wiring certificate was available.

We looked at some of the arrangements for fire safety. Servicing labels on the fire extinguishers showed they had not been serviced for a number of years. A fire risk assessment had not been conducted and fire exits were not signposted. We recommended the registered manager to seek advice regarding these areas from a suitable fire safety expert.

Improvement needed

The service must ensure that all appropriate measures and precautions are in place to protect the health and safety of patients at this service. Specifically, there must be adequate precautions in place against the risk of fire, including a comprehensive fire risk assessment, suitable fire fighting equipment and signage.

Quality of management and leadership

Governance and accountability framework (Standard 1)

Rethink the ink is run by the registered manager.

We looked at a sample of policies and procedures in place. Due to the improvements we identified to policies, as previously mentioned in this report, we recommended that a review of all policies and procedures takes place to ensure they are sufficiently detailed and comply with regulatory requirements.

Improvement needed

All policies and procedures should be reviewed must comply with the regulatory requirements and standards.

Dealing with concerns and managing incidents (Standard 23)

Although details about how the service deals with complaints are included in the patients guide and statement of purpose, a complaints policy was not in place. In accordance with the regulations, a written copy of the procedure should be available upon request to patients.

Improvement needed

A complaints policy must be created in accordance with regulatory requirements.

The registered manager told us that they had not received a formal complaint. However, we observed that patients used the service's Facebook page to express their views. We also saw that the service had responded inappropriately to patient complaints via Facebook which did not protect patient confidentiality and comply with the complaints procedure.

Improvement needed

Complaints must be responded to appropriately, in accordance with the services' complaints policy and in a way that protects the privacy and confidentiality of patient information. Specifically, social media should not be used as a method of responding to complaints.

We advised the service to ensure all informal, verbal and written complaints are recorded, as a way of monitoring the quality of the care provided.

Records management (Standard 20)

The registered manager confirmed that patient information was kept securely in a filing cabinet which was locked. The service is advised to ensure this is locked at all times when not in use.

Workforce recruitment and employment practices (Standard 24)

The registered manager had a Disclosure and Barring Service (DBS) certificates dated within the last three years in line with the regulations, as part of their registration with HIW. We reminded the manager to ensure this was updated in line with regulatory requirements.

No other staff members worked at the service, therefore we did not look at the arrangements regarding workforce recruitment and employment practices at the service.

Given the findings from this inspection, improvements are needed in the quality assurance and governance arrangements of this service to ensure compliance with the relevant regulations and standards.

The operation of sound quality assurance and governance arrangements and a registered provider's timely response to remedy issues of concern are important indicators of a provider's ability to run their service with sufficient care, competence and skill. There is an expectation, therefore, that the registered manager and responsible individual take meaningful action to address these matters, as a failure to do so could result in HIW taking action for non-compliance with regulations.

Improvement needed

There must be effective management and quality assurance systems in place to ensure compliance with the standards and regulations, as a means to meeting the legal obligations to provide safe and effective laser treatments to patients.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan in respect of improvements identified in the report. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at Re-think the ink will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

Improvement Plan

Service: Rethink the ink

Date of Inspection: 11 August 2016

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
6	Improvements must be made to the treatment register to ensure that comprehensive records of treatment are maintained.	Regulation 23 (1) & 45 (2)			
7	The patient's guide must be updated in accordance with the regulations.	Regulation 7			
7	The statement of purpose must be updated in accordance with the regulations. A copy of the updated statement of purpose must be sent to HIW.	Regulation 6 (1) and Schedule 1			
7	There must be a system in place for regularly seeking patient feedback.	Regulation 19 (2) (e) &			

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
		7 (e)			
Delivery of Safe and Effective Care					
8	The local rules should be reviewed to reflect the changes in the equipment in use.	HIW conditions of registration Regulation 15 (1) & (2) Standard 16			
8	There must be suitable arrangements in place to ensure the laser machine equipment is safe, maintained in good condition and can be regularly serviced, as and when this is required.	Regulation 15 (1) & (2); Standard 16			
9	<i>Immediate concern identified during inspection:</i> Patient safety and welfare must be protected. Specifically, an onsite assessment of the safety of the equipment and environment at the service must be conducted by a Laser Protection Adviser.	Regulation 26; 15 (1), (2) and 19(1)(2); NMS Standard 12 & 16	I have contacted my LPA and have arranged a site visit this is now booked in for 5 oct After talking to my LPA he has advised me according to regulations on the blind, this has now been fitted	J Richardson J Richardson	Oct 16 done

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	The report following the onsite visit from the Laser Protection Advisor must be provided to HIW.				
9	<i>Immediate concern identified during inspection:</i> The registered manager must protect patients and any others against the risks associated with the laser beam. Specifically, children must not be admitted into the controlled area while the laser is in use.	Regulation 19 (1); NMS Standard 22	Policies and procedures, and statement of purpose has been updated informing no children allowed in the treatment room. Signs now on display	J Richardson	Done
9	The registered manager should take steps to prevent unauthorised use of the IPL/laser machines, specifically by ensuring the activation keys are stored securely.	Regulation 45 (3) Standard 16, 22			
10	Robust processes must be in place to ensure that children and vulnerable adults who may use the service are adequately safeguarded. Specifically, clear policies and procedures on safeguarding, consent and the treatment of children must be created; safeguarding training should	Regulation 16 Standard 11			

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	be conducted.				
10	The infection control policy must be updated with further details of the cleaning arrangements.	Regulation 9 (n) Standard 13			
10	The service must ensure that all appropriate measures and precautions are in place to protect the health and safety of patients at this service. Specifically, there must be adequate precautions in place against the risk of fire, including a comprehensive fire risk assessment, suitable fire fighting equipment and signage.	Regulation 15 (1),(2); 19(1); 26(5)(b) Standard 22			
Quality of Management and Leadership					
11	All policies and procedures should be reviewed must comply with the regulatory requirements and standards.	Regulation 9			
11	A complaints policy must be created in accordance with regulatory requirements.	Regulation 24			
11	Complaints must be responded to	Regulation			

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	appropriately, in accordance with the services' complaints policy and in a way that protects the privacy and confidentiality of patient information. Specifically, social media should not be used as a method of responding to complaints.	24 Standard 23 Standard 9			
12	There must be effective management and quality assurance systems in place to ensure compliance with the standards and regulations, as a means to meeting the legal obligations to provide safe and effective laser treatments to patients.	Regulation 19 & 9			

Service Representative:

Name (print):

Title:

Date: