

Class 3B/4 Laser and Intense Pulsed Light services

Annual Report 2016 – 2017

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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that people in Wales are receiving good care.

Our values

- **Patient-centred:** we place patients, service users and public experience at the heart of what we do
- **Integrity:** we are open and honest in the way we operate
- **Independent:** we act and make objective judgements based on what we see
- **Collaborative:** we build effective partnerships internally and externally
- **Professional:** we act efficiently, effectively and proportionately in our approach.

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care.

Promote improvement:

Encourage improvement through reporting and sharing of good practice.

Influence policy and standards:

Use what we find to influence policy, standards and practice.

1. Foreword

This is HIW's second annual report for Class 3B/4 laser and Intense Pulsed Light (IPL) services.

The purpose of this report is to summarise the findings from our inspections during 2016-17 and to highlight the areas for improvement and areas of good practice we have identified across services. As a result of the themes identified from our inspections, we have made overarching recommendations for services in this area (Appendix A).

HIW is responsible for the registration and inspection of independent healthcare services in Wales, including Class 3B/4 laser and IPL services. However, it is healthcare service providers themselves who are primarily responsible for ensuring patients receive safe and effective treatments. The Independent Health Care (Wales) Regulations 2011 place legal obligations on service providers in this respect.

We hope that services working in this area will carefully consider the contents of this annual report and our overarching recommendations and use these to make improvements to their services.

2. Summary

Overall, we found that services provided safe and effective care. However, as in 2015-2016 there were common areas of concern regarding compliance with the regulations in the majority of services inspected.

Services providing treatments to patients using Class 3B/4 laser and IPL¹ are registered with HIW as independent hospitals under the Independent Health Care (Wales) Regulations 2011. The majority of these services are provided within beauty salons and clinics for aesthetic skin treatments, such as hair removal, wrinkle reduction and tattoo removal.

HIW inspections of independent healthcare services seek to ensure services comply with the Care Standards Act 2000 and the 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 Wales.

During 2016-17, HIW conducted a total of 23 inspections of Class 3B/4 laser and IPL services across Wales. One of these was a follow-up inspection to assess the progress made in meeting the improvement needed by the service since the initial inspection in 2015.

Whilst we found some areas of improvement amongst the services we inspected this year, it was disappointing to find that the majority of improvements needed were similar to those identified in 2015-2016.

We found some improvements in the following areas:

¹ IPL is a broad spectrum light source technology and is used by cosmetic and medical practitioners to perform various skin treatments for aesthetic and therapeutic uses.

- Arrangements regarding aspects of health and safety including Portable Appliance Testing, premises electrical wiring checks, provision of first aid kits and suitability of eye protection
- Services' arrangements for patients to provide feedback on the services provided
- The number of services with an infection control policy in place

The majority of patients indicated they were very satisfied with the service received when visiting and in receipt of treatment. However, we identified a number of areas for improvement as a result of our inspections. Whilst we found that the majority of services provided safe and effective care, we identified areas of concern at four services where we asked for urgent action to be taken to address issues relating to servicing and calibration of laser equipment, the updating of risk assessments and local rules, implementation of appropriately authorised treatment protocols, physical layout of laser equipment within controlled areas and implementation of a patient treatment register. Following our inspection, one of these services expressed their wish to cancel their registration with HIW as they no longer wanted to continue providing treatments using Class 3B/4 lasers and IPL.

Similar to our findings in 2015-2016, we found again that the majority of services lacked sufficient awareness and understanding of the standards and regulations concerning the provision of Class 3B/4 laser and IPL services. Furthermore, most services did not have effective systems and processes in place to ensure they were meeting the relevant standards and complying with the regulations.

We found that services needed to make improvements in the following areas:

- Providing up-to-date training for staff in the safe use of lasers and IPL
- Ensuring the safe use of laser and IPL equipment including regular servicing, availability of up-to-date local rules and contact with a Laser Protection Adviser
- Arrangements for safeguarding children and vulnerable adults, including safeguarding training and suitable policies detailing clear procedures for staff to follow
- Up-to-date Disclosure and Barring Service checks in accordance with regulatory requirements
- Arrangements for managing risk and health and safety

- Developing and keeping under review the documentation, policies and procedures required by the regulations
- Effective governance and quality assurance systems.

Following our inspections, where necessary, services were required to complete an improvement plan. This was in order to provide HIW with assurance that the findings from inspections had been addressed or to demonstrate that significant progress was being made toward this. Often, we found that the quality of improvement plans were poor and some services failed to provide the plans within the agreed timescale. As we found in 2015-2016, this was often because services had failed to sufficiently familiarise themselves with the requirements of the standards and regulations in order to take appropriate actions. In these cases, we took further action to ensure that services provided HIW with the necessary level of assurance.

Reports on all of our inspections and their associated improvement plans are published on HIW's website. ²

² www.hiw.org.uk

3. What we did

2016-2017 was the second year of an ongoing programme of three yearly inspections of laser and IPL services in Wales, following the introduction of a new inspection approach in 2015-2016. Between April 2016 and March 2017 a total of 23 inspections were conducted across Wales, one of which was a follow-up inspection.

Each inspection was announced (generally four weeks in advance) and conducted by at least two members of HIW staff. HIW was able to offer a placement to a trainee Laser Protection Adviser during the year which proved to be beneficial; the trainee was able to provide advice and support to HIW staff from a professional perspective during a number of inspections. We were able to further develop our inspection methodology and supporting guidance as a result of the placement.

We aim to ensure that the maximum period between inspections for these services is three years. However, services may be inspected more frequently as we take into account findings from previous inspections and information and intelligence we receive when considering our risk based approach to inspection.

Independent healthcare services are responsible for ensuring the quality and safety of the treatments provided. During each inspection, HIW considered whether there were effective systems and processes in place to ensure the service was:

- Meeting the relevant national minimum standards and complying with regulations
- Providing high quality, evidence based treatment and care through services that are patient/service user focussed
- Continually monitoring the quality of treatment and services
- Putting things right quickly, when they go wrong
- Providing treatment and services in accordance with the statement of purpose.
- We published our findings within our inspection reports under three themes:
- Quality of patient experience

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

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

- Information held by HIW
- Interviews with staff (where appropriate) and the 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 provided an overview of our main findings to representatives of the service to ensure that they received appropriate feedback.

Our 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.

HIW took a balanced and proportionate approach with services when seeking action from them to address any improvements identified. Central to this approach, however, was ensuring that patients using these services were not being put at risk. Where HIW has immediate patient safety concerns, it raises and escalates these at the time of the inspection and requests that where possible they are resolved by service staff before the end of the inspection. Where serious regulatory non-compliance is identified resulting in poor outcomes for patients and indicating systemic failing within a service, the registered provider would be notified via a non-compliance notice.

Following each inspection, the service was sent a draft report to check for factual accuracy. Where appropriate, this included an improvement plan for the service to complete, in order to inform HIW of the actions being taken to

address the issues identified. All improvement plans were separately evaluated by HIW to determine whether the service had responded appropriately or if further action was required. Once the improvement plan was agreed, this was published alongside the inspection report on HIW's website.

For the purpose of this report, we refer to the responsibilities of the following groups/individuals:

- Registered manager: A person who is registered under Part II of the Care Standards Act 2000 as a manager of an independent healthcare service. They are locally accountable for ensuring that the service meets National Minimum Standards and complies with regulations
- Registered provider: A person who is registered under Part II of the Care Standards Act 2000 as the person carrying out the independent healthcare service
- Laser/IPL operators: Anyone providing any type of treatment to patients using a Class 3B/4 laser and IPL.

4. What we found

Quality of patient experience

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.

Patients told us that they were happy with the care and treatment provided to them and that they were provided with enough information to be able to make an informed choice about their treatment. The majority of services had appropriate systems in place to allow patients to provide feedback about the treatment received.

We did, however, find that improvements were required to the information recorded by services about treatments given. The majority of services were also required to make improvements to information within their Statement of Purpose and Patient Guide documents, in line with the regulations.

Patient engagement and feedback

Prior to inspection, services were asked to distribute HIW questionnaires to patients to obtain their views about the services provided. The number of completed questionnaires provided to HIW ranged from 4 to 30. We found that this was dependent upon the individual service and the number of patients they had seen in the weeks leading up to the inspection, some services seeing very few patients each week. Four service providers were unable to provide any completed questionnaires. Completed questionnaires indicated that patients were very satisfied with their experiences whilst visiting the services. The majority of patients agreed, or strongly agreed, with statements that services were clean, tidy and that staff were polite, caring, listened, and provided enough information about their treatment.

We saw that the majority of services had a formal system in place to regularly obtain patient views and feedback as a way of monitoring the quality of the

services being provided. Only three did not have any system in place. This was an improvement from the services we inspected in 2015-2016 where the majority did not have a system in place to allow them to obtain patient feedback and views.

Patient information and consent

We found, as in 2015-2016, that services provided patients with appropriate information in order to help them make an informed decision about their care. Typically patients were provided with a consultation prior to treatment and given information about the risks and benefits. Patients were also asked to provide written consent to treatment and complete medical history forms. We found however, that some services were not documenting this information consistently. Whilst services told us verbal discussions were held with patients, we found that some providers were failing to formally record ongoing consent, updating medical histories and countersigning documentation where appropriate.

We found that ten services were not recording appropriate or sufficiently detailed information about each treatment performed. These services were reminded of their responsibilities under the regulations to ensure that comprehensive health care records are maintained for all treatments provided to patients.

Communicating effectively

In accordance with regulatory requirements, all services must have a patients' guide and statement of purpose in place, which detail the types of services and treatments provided as well as other relevant information about the service. Whilst we found that all services had these documents in place, an improvement on the inspection year 2015-2016, we identified improvement was needed in a minority of our inspections to ensure that the documents were accurate, up-to-date and contained all the relevant information.

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

Overall we found that the majority of services were providing safe and effective care. We did, however, make a number of recommendations, similar to 2015-2016, including aspects of health and safety arrangements, safeguarding policies and training for staff, arrangements for Laser Protection Advisers, appropriate medical protocols in place and arrangements for maintenance of laser/IPL equipment.

As a result of inspection, four services were reminded of the need to take prompt action to address concerns. One service confirmed their intention to cease providing services requiring registration.

Managing risk and promoting health and safety

Overall, we found that the majority of services had appropriate arrangements in place relating to health and safety provision. Unlike in 2015-2016, we found that all services had the following in place:

- Regular completion of Portable Appliance Testing (PAT)
- Evidence of five yearly wiring check of the premises
- Availability of appropriately stocked first aid kits
- Suitable eye protection for patients, IPL/laser operators and potential chaperones.

As in 2015-2016, we did find that improvements were required in nine services to their fire safety arrangements. This included completion of comprehensive fire risk assessments, ensuring appropriate signage of fire exits, regular servicing of fire extinguishers and completion of fire drills. Where appropriate, we recommended to services that they obtain appropriate advice in relation to fire safety provision at their premises to ensure they were compliant with relevant guidelines.³

We also found, similar to 2015-2016, that improvements were required to services' environmental risk assessments. Whilst the majority of services we inspected had an environment risk assessment in place, we found that eight required improvement, including not being sufficient detailed, not signed, dated or appropriately reviewed.

We found that whilst the majority of services prevented unauthorised access to treatment rooms, we highlighted to three service providers where improvement was required to ensure that keys for IPL/laser machines are removed to prevent unauthorised use.

Registered persons were reminded about their responsibilities under the regulations to ensure that all appropriate measures and precautions are in place to protect the health, safety and welfare of patients and staff.

Infection prevention and control

Overall we found that services were visibly clean and tidy and had suitable arrangements in place for infection prevention and control. We found only two services that did not have an infection control policy in place, an improvement on 2015-2016. During a number of inspections we were told of the detailed arrangements in place for cleaning and infection control, however, the policies and procedures did not always reflect the work being carried out. On a number of occasions we required service providers to make improvements to their policies to ensure they were reviewed and up to date to fully reflect the work being undertaken.

³ Regulatory Reform (Fire Safety) Order 2005

Safeguarding children and adults at risk

We found that improvements were needed to the arrangements for safeguarding children and vulnerable adults at many of services we inspected. Similar to our findings in 2015-2016, updates to adult and child safeguarding policies were required to ensure they provided clear and sufficient information when needed. It was disappointing to find that six services did not have a policy in place at all. We also found that over half of registered managers and laser/IPL operators had not attended safeguarding training.

We found a significant improvement in the number of services having conducted Disclosure and Barring Service (DBS) checks on relevant staff. We found improvement was needed at three of the 23 services we inspected. This compares to 15 of 19 services inspected in 2015-2016 that did not hold valid DBS certification.

Medical devices, equipment and diagnostic systems

It is a requirement for each service to have a Laser Protection Adviser in place; to provide advice and guidance on the safety of the environment, equipment and its day-to-day operational use. This is fundamental to the safety of patients receiving treatment. HIW expects a Laser Protection Adviser to review these areas at least annually in order to meet this requirement.

We found that all services had a contract in place with a Laser Protection Adviser, an improvement on 2015-2016 where two did not. Whilst 13 of the services had received a visit from their Laser Protection Adviser to enable a thorough environmental risk assessment and review of the local rules to take place, we were concerned to find that the remaining services received their support from the Laser Protection Adviser remotely, replacing a site visit. Assessments were conducted via telephone, email and through photographs of the environment. Similar to our findings in 2015-2016 we found in a number of these cases that the Laser Protection Adviser had not visited the service for a number of years and concerned to find that some of the potential hazards had not been assessed sufficiently, such as window blinds not being sufficient to prevent laser light from escaping the controlled area and therefore a potential for causing harm. We recommended, where an onsite visit had not been conducted by a Laser Protection Adviser, that services should arrange for a visit to take place to ensure that all hazards relating to the environment and equipment were appropriately assessed for the safety of both patients and staff.

For each laser and IPL machine in use, there must be local rules in place which detail the safe use of the equipment. It is a requirement of HIW registration that the local rules must be reviewed at least annually by the Laser Protection

Adviser. We found that the majority of services had local rules in place which were signed by the Laser Protection Adviser and all operators to show their awareness and agreement to follow these rules. However, four of the services were required to review and update their local rules as they had not been reviewed within the last 12 months.

It is a requirement that all services have up-to-date medical/treatment protocols in place that are signed by an expert medical or dental professional. We found that one service did not have any in place and a further eight were either unsigned by a relevant medical or dental professional or required to be reviewed and updated.

Regular training is important to ensure anyone providing treatments using a laser/IPL is fully aware of the risks and safety requirements associated with their use. Failure to attend regular training may mean that laser and IPL operators do not have the skills necessary for performing treatments safely

We found in the majority of services that staff providing treatments had received up to date training in laser and IPL safety known as Core of Knowledge⁴ and had also completed training in the correct use of the machines (usually provided by the manufacturer). We needed to remind two services of their responsibility to ensure that staff renew their Core of Knowledge training within a three year period, services agreed to address these issues.

In accordance with regulatory requirements, all equipment must be safe, maintained in good condition and suitable for use. Whilst fourteen services were able to provide confirmation of servicing and calibration of their laser and IPL machines, we found that the remaining either needed to obtain clarification of the servicing requirements from the manufacture, servicing was out of date, or the equipment was new. Where appropriate, services were reminded of their responsibility to ensure that equipment remained safe to use.

⁴ 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.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how service providers review and monitor their own performance against the National Minimum Standards.

Overall, we found that there was a continued lack of understanding and awareness by services of the standards and regulations regarding the provision of Class 3B/4 laser and IPL treatments. Improvements were required in the majority of services regarding quality improvement activity and in the continued quality of policies and procedures in place.

Governance, leadership and accountability

Services providing treatments to patients using a Class 3B/4 laser and IPL are registered with HIW as independent hospitals. However, the majority of these services are provided within non medical settings such as beauty salons and clinics for aesthetic skin treatments (e.g. hair removal, wrinkle reduction and tattoo removal).

Similar to our findings in 2015-2016, we were again disappointed to find that the majority of services lacked sufficient awareness and understanding of the standards and regulations regarding the provision of Class 3B/4 laser and IPL services. Given the findings from our inspections, most services did not have effective systems and processes in place to ensure they were meeting the relevant standards and complying with the regulations. Seventeen services inspected were reminded of their responsibilities to ensure they had sufficient quality assurance and governance arrangements in place to meet compliance with the relevant regulations and standards.

Whilst we found that all services had relevant policies and procedures in place, an improvement from the services inspected in 2015-2016, the majority required amendments to ensure they were up to date and include appropriate, detailed information and guidance.

Dealing with concerns and managing incidents

We found that one service did not have a complaints policy in place, and a small number of services were required to update their policy to ensure it was in line with the regulations. The majority of the services had not received a complaint. We reminded them of the importance of documenting any type of complaint received (both verbal and written) in order to be able to resolve concerns and identify any emerging themes and improve practise as an outcome.

Records Management

Overall, we found that patients records were stored securely by the services we inspected in order to maintain confidentiality. We made two recommendations where improvements could be made regarding some security arrangements.

Staff and resources

Workforce recruitment and employment practices

Similar to our findings in 2015-2016, in many of the services we inspected, laser and IPL treatments were conducted by the registered manager only, therefore information relating to workforce planning and training arrangements (i.e. induction and appraisals) did not form part of these inspections.

We found that the majority of services had appropriate checks in place i.e. a Disclosure and Barring Check (DBS) for registered managers and laser operators. Where appropriate, we generally found that services had suitable processes in place to ensure that staff had access to appropriate training, regular appraisals and team meetings.

5. Conclusions

Whilst we found some areas of improvement in the services inspected in 2016-2017, including some health and safety provision, infection control policies and the ability for patients to provide feedback, overall the majority of issues identified were reflective of our findings in 2015-2016. We again concluded that the areas for improvements identified across the services were indicative of registered providers' lack of awareness and understanding of the standards and regulations regarding the provision of Class 3B/4 laser and IPL services. Despite the obligations upon these businesses to ensure that the services they provide meet the necessary standards and regulations, it was evident that many providers did not ensure that the arrangements and documentation required upon registration were maintained on an on-going basis.

A potential contributory factor to these issues is that the majority of services registered with HIW are provided by non-medical professionals, many of whom have little or no prior experience of working within regulated sectors. Those providers who are from a non-medical background do not have the support of a professional body (such as the General Dental Council for dentists or the General Medical Council for doctors) to assist them with continuing professional development and regulatory compliance, in order to provide safe and effective care.

Through our discussions during inspections, it appeared that many registered providers were not aware of the ongoing financial, managerial and time commitments needed to effectively run their service and meet the necessary requirements. The business implications of this were particularly evident within smaller services that treated relatively few patients.

6. What next?

HIW will continue to follow-up on our previous inspections in the forthcoming year to seek assurance that services have taken sufficient action to address any identified areas for improvement. HIW will also consider, if appropriate, whether further action, including enforcement action, is necessary should service providers fail to take necessary steps to address improvement areas.

HIW will continue the work started in 2015-16 to consult further with a Laser Protection Adviser with regards to our inspection approach. HIW will be considering the option of using a peer reviewer during inspections as a developmental approach to our inspection activity.

The way in which laser providers are regulated in the future may change following the review of HIW's legislative framework proposed in the Welsh Government's White Paper 'Services fit for the future; Quality and Governance in health and care in Wales'. HIW will await the outcome of the consultation process and adapt its approach accordingly.

HIW will continue to investigate intelligence received regarding unregistered services which may be providing laser and IPL services and could need registration. Any settings which continue to provide Class 3B/4 laser or IPL services without being registered will be considered for further action under HIW's enforcement process

Appendix A – Recommendations

As a result of the findings from our 23 inspections in 2016-2017, we have made the following overarching recommendations which all services should consider as part of providing a safe and effective service.

Whilst we have seen some areas of improvement in services inspected in 2016-2017, it is disappointing that the majority of recommendations are reflective of those made in 2015-2016.

Recommendations	Regulation / Standard
Patient Experience	
Comprehensive health care records and a register of all treatments performed must be maintained.	Regulation 23 and 45
A patient's guide and statement of purpose must be kept under regular review to ensure it captures relevant and detailed information.	Regulation 6 and 7
Delivery of safe and effective care	
A Laser Protection Adviser must be in place who assesses and advises on the safe use of laser/IPL equipment and operational use at least annually, and as required.	Regulation 15 and 19 Standard 16
All laser/IPL operators must have up-to-date training in the use of this equipment and in Core of Knowledge.	Regulations 45 (3) Standard 25
All equipment must be maintained in a safe and suitable condition, including the regular servicing of laser/IPL machines.	Regulation 15
Local rules must be in place and reviewed at least annually by a Laser Protection Adviser.	HIW conditions of registration Regulation 15 Standard 16

Recommendations	Regulation / Standard
Treatment/medical protocols must be in place and signed by an appropriate expert medical practitioner	Regulation 45
Robust processes must be in place to ensure the welfare and safety of children and vulnerable adults who may use the service. Including, staff training in this area and adequate policies and procedures.	Regulation 16 Standard 11
All appropriate measures and precautions must be in place to protect the health and safety of patients, including all appropriate fire safety measures and comprehensive risk assessments.	Regulation 15, 19 and 26
Quality of management and leadership	
Services must have effective management and quality assurance systems in place to ensure compliance with the standards and regulations, to ensure safe and effective laser treatments are provided to patients.	Regulation 19
Policies and procedures must be in place in accordance with regulatory requirements and kept under review.	Regulation 9
All registered persons and laser/IPL operators should have an up-to-date DBS certificate.	Regulation 12, 21 and Schedule 2