

Annual Report

Class 3B/4 Laser and Intense Pulsed Light services 2017–2018



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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 receive good quality care.

Our values

We place patients at the heart of what we do. We are:

- Independent
- Objective
- Collaborative
- Authoritative
- Caring

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 third 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 2017-18, 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 expect all services working in this field to carefully consider the contents of this annual report and our overarching recommendations. The key aim of this annual report is for services to utilise the recommendations as a foundation for improving their services, and for the public to have assurance that HIW is continually monitoring services to ensure best possible outcomes.

2. Summary

Overall, treatment was provided in a patient focussed way, with services aiming to provide the best possible outcomes for their patients. We highlighted that care and treatment practices were largely safe and effective, however, as referenced in our 2016-17 report, we continue to note concerns regarding compliance with certain components of the regulations.

Services providing treatments to patients using Class 3B/4 laser and IPL¹ are required to register with HIW as independent hospitals under the Independent Health Care (Wales) Regulations 2011. As identified in previous annual reports the majority of these services are provided within beauty salons and clinics for aesthetic skin treatments, such as 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 2017-18, HIW conducted a total of 25 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 required since the initial inspection in 2015.

We found areas of improvement amongst the services we inspected this year, however it was disappointing to find that the majority of improvements needed were similar to those identified in 2016-17.

Areas of good practice were highlighted in the following areas:

- patients felt well informed of their treatments and what were the expected outcomes
- patients felt well placed to make an informed decision regarding the best treatment options available
- premises were noted as being very hygienically clean, tidy and well organised.

As highlighted last year, the vast majority of patients told us that they were very satisfied with the treatments provided. However, we also identified areas of concern at seven services which required the issuing of non-compliance notices. These non-compliance notices required urgent action to be undertaken to address issues relating to the calibration and regular servicing of laser equipment, evidence of specialist training for staff in the use of laser equipment. One setting was not compliant with the conditions of their registration as laser equipment was being used which had not been registered for use.

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.

Additional non-compliance issues included the requirement for risk assessments and local rules to be updated, inadequate patient documentation and records, timely support of a laser protection advisor, and arrangements for the maintenance of fire safety equipment, namely fire extinguishers. We also identified three other areas of concern, although these did not necessitate the requirement for a non-compliance notice to be issued as they did not directly pose a risk to patients.

Generally, we found that services needed to make improvements in the following areas:

- providing up-to-date training for staff, in particular safeguarding
- 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
- developing and keeping under review the documentation, policies and procedures required by the regulations, such as service user guides and statements of purpose
- effective governance and quality assurance systems.

Following all but one of our inspections, services were required to complete an improvement plan. This was in order to provide HIW with assurance that the findings from our inspection had been addressed, or to demonstrate that significant progress was being made toward this. This year we noted the quality of improvement plans submitted was better in comparison with 2016-17.

Reports for all of our inspections and their associated improvement plans are published on HIW's website².

Enforcement

Where registered services continue to be non compliant, we will consider further action, which includes imposing conditions on a registration and ultimately cancelling their registration. This year HIW have cancelled the registration of some providers who have not worked with us.

When HIW becomes aware of a provider who may be providing services without being registered, we write to them to gather further information on the service being provided so that we can be clear on whether registration is required.

If a service works with us and stops providing any services until they are registered then we will work with them, but if any services refuse to stop then we will consider taking criminal action.

² www.hiw.org.uk

3. What we did

2017-18 was the third 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 2015-16. Between April 2017 and March 2018 a total of 25 inspections were conducted across Wales.

Each inspection was announced (approximately four weeks in advance) and was conducted by two members of HIW staff.

We aim to ensure that the maximum period between inspections for these services is three years. However, services may be inspected more frequently if we take into consideration findings from previous inspections, or in line with our risk based approach we receive information from concerns that gives us cause to inspect sooner.

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 every inspection, we provided an overview of our main findings to representatives of the service to ensure that they are informed about good practice, and areas of concern requiring improvement. In-depth findings are provided in our reports.

Our inspections of laser services provide a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

HIW undertakes a balanced and proportionate approach with services when seeking action from them to address any improvements identified. Central to this approach, however, is ensuring that patients using these services were not being put at risk. Where HIW identifies 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 are fully 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 either in the inspection report or as a separate document 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.

Overall, we were informed by patients during our discussions, and in feedback received from questionnaires, that they were happy with the care and treatment provided. Patients were provided with good quality, accurate information of their proposed treatments in order to make informed decisions. We identified that staff were well informed and would provide patients with advice and guidance about their treatments, and what was to be expected as a consequence of their treatment.

The majority of services had comprehensive systems in place to enable patients to provide feedback about the treatment received.

However, again this year we found that improvements were required in relation to the information contained within their Statement of Purpose and Patient Guide documents, which are requirements of the regulations.

Patient engagement and feedback

In line with all of our announced inspections, services were requested to distribute HIW questionnaires to patients to obtain their views about the services provided. Completion of these questionnaires 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. Questionnaires returned to HIW identified that patients were very satisfied with their experiences and the treatment provided by the services. Almost all respondents agreed, or strongly agreed, with statements that services were clean, and tidy. Respondents also felt that staff were professional in their approach, polite, caring, and provided sufficient information of treatment options available to them.

We noted that there have been improvements since last year in the methods services used to obtain feedback from patients. All services, apart from one, had processes in place to monitor patient satisfaction with the services provided.

Patients felt enabled to approach members of staff with any questions in relation to their treatments and identified that the information received was of a good quality.

Patient information and consent

Services provided patients with appropriate information in order to help them make an informed decision about their care. Services had process in place to ensure that patients consented to planned treatments. Patients were provided with a consultation prior to treatment in order to make informed decisions and given information about the risks and benefits.

Some discrepancies were identified during our inspections in the formal documentation of patients' medical histories, which are essential components to ensure appropriate care and treatment was provided. These issues were raised to providers and action plans developed in order to ensure safe and effective care.

Information was provided to patients in a range of formats. Leaflets and advice sheets were freely available.

Communicating effectively

In accordance with regulatory requirements, all services are required to have a patients' guide and statement of purpose, which details the types of services and treatments provided, as well as other relevant information about the service. These key documents provide information for patients about the formal policies and procedures in operation and information in regards to treatment options available. Whilst all services had these documents in place, as last year, we identified improvement was needed 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 are confident that the majority of services we inspected were delivering safe and effective care and treatments to patients. Services had developed effective treatment practices and procedures bespoke to the needs of the patient.

One area which posed significant concern was the need for services to ensure that staff received adequate adult safeguarding training and the incorporation of processes to ensure vulnerable adults are safeguarded appropriately.

Managing risk and promoting health and safety

Overall, we found that the majority of services we inspected had appropriate processes in place ensuring health and safety provision. We noted as per our 2016-17 inspections that 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.

Fire safety arrangements have improved since our previous two annual reviews. Almost all services had the required fire safety precautions and servicing arrangements in place. Appropriate fire risk assessments, signage, regular servicing of fire extinguishers and completion of fire drills were undertaken at regular timely intervals as required by the

regulations. However, three services had fire safety risk issues which required improvement. One required the advice of specialist fire safety expert in relation to the location of fire extinguishers, signage and emergency exits. The second service did not have satisfactory documentation to demonstrate that timely servicing of fire equipment had been undertaken, and thirdly a service was required to ensure that all fire risk assessments had been dated.

We identified that services had access to a first aid kit, and we found the contents to be within their expiry dates and fit for purpose. We also saw certificates to evidence that staff had also received appropriate first aid training.

As per previous years, registered persons were reminded about their responsibilities to ensure that the regulations are adhered with 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

All services apart from one had suitable in-depth policies, procedures and waste disposal contracts available in relation to the prevention and control of infection. The one service identified with inadequate infection process in place was required to improve their performance in this area to ensure safe and effective practices.

Respondents to our questionnaires identified that they were happy with the environments in which treatments took place. Cleanliness and the organisation of rooms were also noted as good by our inspections. Appropriate cleaning schedules were available for scrutiny in all inspections apart from one, however, the premises were hygienically clean neat and tidy. Registered services have a responsibility to constantly monitor and review infection prevention processes in order to continue to provide safe and effective care and treatment for their patients. Comprehensive waste management procedures and disposal contracts were available at all but one service.

Safeguarding children and adults at risk

Unfortunately, again this year we identified that improvements were required regarding the arrangements for safeguarding vulnerable adults at many of services we inspected. We identified that nine of the twenty five services inspected had insufficient procedures and training in place for ensuring that vulnerable adults are safeguarded. This is an issue of concern and must improve. We intend to scrutinise this issue closely during the next inspection year.

It was positive to report that all services inspected had the appropriate disclosure and barring services (DBS) checks in place on all staff working at the services. This is a significant improvement upon previous years and ensures that only appropriate persons are providing care and treatments to patients.

Medical devices, equipment and diagnostic systems

It is a regulatory 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 requirement is fundamental to ensure that patients are receiving the most up to date and safe care treatments when the use of lasers are involved.

Apart from one, all services had a contract in place with a Laser Protection Adviser. All services should arrange for a visit to take place by a Laser Protection Adviser 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 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, this represents a deterioration with seven services, compared to four from last years annual report, where we identified a requirement to review and update their local rules as they had not been reviewed within the last 12 months.

As noted in previous annual reports, the provision of professional, experienced well informed staff is key to providing high standards of care and treatment. It is a requirement of the regulations to ensure that all practitioners keep up with new and best practice developments. Essential to this aim is for all pertinent staff to attend mandatory and specialist training such as manufacturers training, first aid, laser protection and adult safeguarding. Appropriate and comprehensive training provisions are essential components to ensure the safety of patients and the effectiveness of the services provided. Service providers have a legal responsibility to provide these courses and promote the best possible outcomes for patients. Our inspections identified that not all service providers were providing staff with key essential training.

Service providers have a legal responsibility to ensure that all equipment is maintained and serviced appropriately. Again this year we identified in our inspections that four of the twenty five services had insufficient evidence that their laser equipment had been calibrated and maintained appropriately. Services were reminded of this during inspections and recommendations issued accordingly.

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 identified that structures were in operation to ensure the smooth operation of services.

Comprehensive processes were in place to ensure the safe recruitment of staff. However, we did identify the need for some services to provide more detailed and structured appraisals for staff, in order to ensure careful monitoring of their performance and training requirements for the year ahead, as would be identified during a meaningful annual appraisal. This area does require all services to be engaging with their staff in order to ensure effective staff practices are maintained.

It was pleasing to see that the vast majority of services placed an emphasis on concerns and complaints management as a key feature in quality improvement and assurance.

Quality assurance practices were in operation within most services and are a key component of the regulations. Practices are advised to prioritise this area of quality improvement in order to promote best practice.

Governance, leadership and accountability

Services providing treatments to patients using a Class 3B/4 laser and IPL are registered with HIW as independent hospitals. 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).

All but five of the services inspected had satisfactory procedures in operation to ensure regular quality appraisals of the services provided. The five services with insufficient quality revision processes in operation were asked to develop improvement plans. One was also issued with a non-compliance notification.

As identified in the previous two annual reports we found that all services had relevant policies and procedures in operation. However, six services were recommended to improve and update their policies and procedures in order to be valid and in adherence with current best practices. Service providers have a responsibility to ensure that all of their policies are up to date, valid, and contain detailed information and appropriate guidance.

Dealing with concerns and managing incidents

We identified that all services had complaints policies and procedures in operation. We found that services had robust complaints procedures in place and that services had suitable processes in place for dealing with and recording complaints appropriately, demonstrating learning from any concerns or complaints raised. One service was recommended to update their concern policy as it needed more detail such as including timescales for acknowledging and responding to a complaint, and including the name of the individual whom patients could contact in the event of them wanting to raise a complaint.

Records Management

We saw that all records were being stored safely and securely and all computers were password protected to prevent unauthorised access and promote confidentiality.

Staff and resources

Workforce recruitment and employment practices

As part of our inspection activity we reviewed staff files and overall we saw comprehensive staff recruitment processes in operation. However, four of the inspections conducted revealed that staff appraisals were being undertaken regularly. Recommendations were made to improve this component of staff performance management as it enables a comprehensive review of staff development and training requirements.

Staff meetings were being undertaken at all services and these meetings were generally well minuted in order to provide a clear audit trail of discussions held and actions to be undertaken.

We identified that the vast majority of services had a comprehensive detailed induction programme in operation for new staff, to help support them into a new role. This included training provided within the clinic and also head office training covering aspects of health and safety, manual handling, information governance.

5. Conclusions

During the 2017-18 inspections undertaken by HIW, improvements have been identified, with services taking greater care in ensuring patients details and records were stored safely and securely, preventing unauthorised access.

Overwhelmingly, feedback received from patients was complimentary and identified that they were happy with the care and range of treatments received.

However, again this year it is disappointing to highlight that services are not meeting all the designated standards and regulations. Common themes continue to occur, which is unsatisfactory and demonstrates a weakness in applying learning to improve services. Services must place a greater emphasis on continuous improvement of the standards of care and treatments provided, and to ensure the best possible experiences and outcomes for patients. A lack of consistent updating of essential core documents was one of the themes to emerge again this year. Services are required by regulations to continually review and revise core documents such as Statements of Purpose and Service Users Guides. Registered providers must adhere with regulations to ensure that patients are fully informed of the services being offered and the likely outcomes of treatments.

Safeguarding training is a significant area that must be improved upon. Services have a responsibility to ensure that staff are fully aware of safeguarding issues and that best practice guidance is followed stringently. Providers have a duty to all patients that enter their premises to ensure that their wellbeing and welfare are fundamental key components of a safe and effective service provision.

6. What next?

A copy of this report will be sent to all registered managers of Class 3B/4 services. We expect them to review their service against the issues identified in this report, particularly those that surface year on year, and ensure they are not prevalent in the service they manage.

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.

In February 2018 the Welsh Government published their response to the public consultation on a White Paper titled '*Services fit for the future; Quality and Governance in health and care in Wales*³'. This confirmed the intention to review the legislative framework that underpins HIW's work. This may result in a change to the way the cosmetic laser industry is regulated however the timing of this change is not yet clear.

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.

At the core of all our work is to ensure patients safety, and this is highlighted in our Strategic Plan 2018 – 2021.

Our goal is to:

Encourage improvement in healthcare by doing the right work at the right time in the right place; ensuring what we do is communicated well and makes a difference.

We will focus on 4 main priorities:

1. To maximise the impact of our work to support improvement in healthcare.
2. To take action when standards are not met.
3. To be more visible.
4. To develop our people and organisation to do the best possible job.

³ <https://beta.gov.wales/sites/default/files/consultations/2018-02/180226summary-of-responses.pdf>

Appendix A

Recommendations

As a result of the findings from our 25 inspections in 2017-18, we have made the following overarching recommendations which all services should consider as part of providing a safe and effective service.

Patient Experience	
Recommendations	Regulation/Standard
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	
Recommendations	Regulation/Standard
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
Local rules must be in place and reviewed at least annually by a Laser Protection Adviser.	HIW conditions of registration Regulation 15 Standard 16
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
Quality of management and leadership	
Recommendations	Regulation/Standard
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

Quality of management and leadership	
Recommendations	Regulation/Standard
Policies and procedures must be in place in accordance with regulatory requirements and kept under review.	Regulation 9
Services must provide all appropriate staff comprehensive safeguarding training in order to ensure that patients' wellbeing is promoted at all times.	Regulation 20 Standard 7.1 Workforce