Independent Healthcare Inspection Report (Announced)

Signature Clinic, Cardiff

Inspection date: 17 July 2023

Follow up date: 7 September 2023

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

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

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

- Independent we are impartial, deciding what work we do and where we do it
- Objective we are reasoned, fair and evidence driven
- Decisive we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive we value and encourage equality and diversity through our work
- Proportionate we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.



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1. What we did

Full details on how we inspect the NHS and regulate independent healthcare providers in Wales can be found on our <u>website</u>.

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Signature Clinic on 17 July 2023. We performed a follow-up inspection on the 7 September 2023.

Our team for the initial inspection comprised of two HIW Healthcare Inspectors and one clinical peer reviewer. We performed a focused follow up inspection in which the team comprised of one HIW Healthcare Inspector and a clinical peer reviewer.

Note the inspection findings relate to the point in time that the inspection was undertaken.

During the initial inspection in July 2023 we found that Signature Clinic was in breach if its conditions of section 24 of the Care Standards Act 2000 regarding failure to comply with conditions of registration. This was because evidence was found that the clinic had been performing services outside the scope of its registration which is an offence. This triggered HIW's enforcement policy and was dealt with separately to the inspection.

This (full) report is designed for the setting, and describes all findings relating to the provision of high quality, safe and reliable care that is centred on individual patients.

A summary version of the report, which is designed for members of the public can be found on our website.

2. Summary of inspection

Quality of Patient Experience

Overall summary:

We found that the registered manager and staff at the clinic worked to provide a positive experience for patients to receive cosmetic procedures. However, we raised significant concerns around infection prevention and control, decontamination and the safe management of patients both intra and post operatively. This was dealt with through our non-compliance process which included a follow up inspection.

Patients were provided with a range of information both pre and post treatment to enable them to make an informed decision. However, there was no health promotion information displayed.

The clinic ensured easy access to patients with mobility issues which included bathroom facilities suitable for patients with mobility access requirements. In addition, staff at the clinic had undertaken training in equality and diversity.

This is what we recommend the service can improve:

- Information on how to provide feedback should be displayed within the clinic.
- The clinic should display information on how patients could help their health and wellbeing.
- Update the Statement of Purpose and Patient Information leaflet to include up to date information.

This is what the service did well:

- Making information available for patients regarding treatments provided at the clinic including pre and post-treatment care information.
- Providing an inclusive environment where patients with protected characteristics are treated equally.
- There was a comprehensive website with details on each procedure. This information was available in hard copy on request.

Delivery of Safe and Effective Care

Overall summary:

Overall we were not assured that the processes at the clinic were safe and effective. We identified areas that were not compliant with the regulations and therefore resulted in a non-compliance notice being issued.

We found evidence that the clinic was performing procedures outside of those agreed in their condition of registration which resulted in an urgent suspension of their registration with Healthcare Inspectorate Wales.

A non compliance notice was issued following the inspection in July 2023. This related to the infection prevention and control processes (IPC) in place. Sufficient assurance was provided at the follow up inspection in September 2023. Further details of the immediate improvements and remedial actions can be found in Appendix B.

Immediate assurances:

- We were not assured that the cleanliness in the surgical theatres was conducive of a sterile environment
- The monitoring of patients during procedures was insufficient.
- The way in which patients accessed urgent medical advice after their procedure was inadequate.
- The decontamination process did not assure us that instruments were appropriately sterilised between patients.

This is what we recommend the service can improve

- Resuscitation training should be delivered by a suitably qualified training provider.
- Ensure the safe keeping of keys to access medication.

This is what the service did well:

- Patients' medical records were found to be clear, securely stored and contained the relevant information that is expected.
- The service used cleaning schedules to ensure all areas of the clinic were regularly cleaned.
- We saw that Personal Protective Equipment (PPE) was available for staff to use.

Quality of Management and Leadership

Overall summary:

Overall, we found that the clinic's governance and leadership was clear and structured. However, there was not always a manager on site when the clinic was open and performing surgery.

The registered manager appeared keen to promote communication within the team to ensure productive working relationships. We saw evidence that staff meetings were held regularly and minutes were recorded.

We saw that mandatory training had been completed by staff and the clinic kept track of training renewal dates with a purpose made database.

We saw that staff had regular appraisals and were told that they could access further training and courses if requested. However, we were unable to speak to staff to confirm this.

Immediate assurances:

 We could not be assured staff were suitably qualified, skilled and experienced to assist in surgical procedures which include checking medication.

This is what we recommend the service can improve on:

- The registered manager must ensure the staff at the clinic are appropriately qualified and skilled
- The service would benefit from management on site to oversee issues as they arise and manage governance

This is what the service did well:

- We saw a wide range of policies and procedures to underpin processes at the clinic.
- Staff received a variety of mandatory training
- There were regular team meetings held and minutes were recorded and disseminated to the wider team.

Details of the concerns for patient's safety and the immediate improvements and remedial action required are provided in $\underline{Appendix B}$.

3. What we found

Quality of Patient Experience

Patient Feedback

Before our inspection we invited the setting to hand out HIW questionnaires to patients to obtain their views on the service provided at the clinic. In total, we received only 2 completed questionnaires. The completed questionnaires were from patients who had been a patient at the clinic for up to one year.

Some of the comments provided by patients on the questionnaires included:

"Very informed on procedure and during the procedure. Excellent after service has really impressed."

Health protection and improvement

There was a lack of health promotion information displayed at the clinic. However, there is a website which details the services available including information of each treatment or procedure. We saw that patient information leaflets were available in reception detailing procedures that were available at the clinic.

Dignity and respect

We saw that Signature Clinic had two treatment rooms situated on the ground floor. Each treatment room had an adjoining assessment room where patients could remove clothing and have their pre-operative pictures taken in private. All rooms had lockable doors. We found the rooms to be tidy and uncluttered. However, we found the IPC standards in the treatment rooms to be below the acceptable level required.

This issue was dealt with under HIW's non-compliance process and is referred to in Appendix B of this report.

There were no windows, so rooms could not be viewed from outside the clinic. Although, there were no privacy screens or curtains in either of the rooms to provide privacy for patients to change.

We recommend using screens or curtains to maintain patients' dignity when changing before their procedure.

The service did not see any patients on the day of our inspection; however, we were told that patients are greeted on arrival and informal introductions are made with staff.

Communicating effectively

The registered manager provided us with copies of the clinic statement of purpose and patient guide. We noted that the statement of purpose required updating to ensure it contained all the accurate and required information. An updated version of this was provided by the registered manager after the follow up inspection and was found to contain the correct information.

There was no information available in Welsh and no policy to detail what actions are to be taken in the event that a client wanted information in Welsh. We were told that a translator would be used if required.

We were told that clients book appointments through the bookings and marketing team. Clients are then contacted by a consultant remotely. Patients then have a face-to-face consultation with the surgeon on the day of the procedure. The registered manager stated that patients are provided with detailed information about the procedure and the process of the day of the procedure. This is emailed to them prior to their procedure taking place. Hard copies of this information can be provided upon request.

The clinic also had an informative website with details about each procedure. We were told that patients were welcomed to ask questions at any stage of the journey through the telephone helpline and a doctor would provide a response.

Patient information and consent

The registered manager and consultants ensured patients were provided with detailed information pre and post treatment so they could make informed decisions about their treatment.

We were told that patients were provided with a variety of detailed verbal and written information both pre and post treatment to ensure they could make an informed decision about their treatment. The clinic used digital medical records which included comprehensive and detailed information around patient consent.

As previously mentioned, the clinic had an informative website that listed treatments available and what they entailed. The registered manager stated that patients unable to access this information digitally would be provided with hard copy information.

Care planning and provision

Staff described that written and verbal information about care and treatment was provided to patients as part of the care planning process. Staff confirmed that delays in patients being seen on the day of their appointment at the clinic were rare. If there was an unavoidable delay, staff confirmed patients would be informed.

The registered person described the arrangements for assessing patients prior to performing procedures, during the procedure and discharging patients following their procedures. We were not assured that these arrangements were safe and sufficient for the procedures being carried out.

This issue was dealt with under HIW's non-compliance process and is referred to in Appendix B of this report.

During the follow-up inspection, the registered manager explained the reviewed and updated process in which patients were assessed. We were assured that patients were safely managed.

Equality, diversity and human rights

We saw an Equality and Diversity Policy and were told all staff complete equality and diversity training. We were told that the clinic was an inclusive environment irrespective of any protected characteristic. We were assured that the human rights of transgender patients would be actively upheld, and preferred pronouns would always be used.

The clinic benefitted from level access with wheelchair accessible doorways. Treatment rooms were large and situated on the ground floor with wide doorways. The clinic had an accessible toilet situated on the ground floor near to the entrance.

The clinic did not have a hearing loop for patients with hearing difficulties. To ensure that patients individual needs are met the patient can bring a chaperone to the clinic to assist with communication needs.

Citizen engagement and feedback

We were told patients were contacted by the aftercare team after their procedure and requested to give feedback on their experience. Patients are also encouraged to give feedback on Google reviews.

We did not see any evidence of feedback displayed in the clinic. We saw that information on how to provide feedback were detailed in the patient guide and statement of purpose, however this was not displayed in the clinic. We were

provided with a copy of the complaints policy which had been recently reviewed and contained details of HIW as required in the regulations.

The registered manager showed us how a record of feedback is kept in a log along with an action plan where they have made changes as a result of feedback received.

Delivery of Safe and Effective Care

Managing risk and health and safety

Signature clinic is a part time clinic opening seven days each month. Their usual working hours were between 8am and 10pm. We were instructed that there are no staff on site when the clinic was closed.

The clinic was situated in a business park with parking available. The clinic is on the ground floor and accessed through a secure intercom system on a shared front door. The clinic environment was warm and welcoming. The general ambience in the waiting room was of a high standard and thought had been put into the layout.

We found the reception area to be well maintained, light and spacious. There was plenty of seating and refreshments available for patients. Toilet facilities were situated near to the entrance and were suitable for patients with mobility issues. These were found to be clean and well maintained.

We saw the clinic environment was well maintained and surfaces allowed for adequate cleaning. However, the cleanliness within the clinical areas was below the standard required for surgical procedures to be carried out. This is detailed in the Infection Control section of this report.

The clinic had a number of policies and procedures in place. The clinic used a computer program, pCloud to store these along with medical records which could all be accessed by every Signature Clinic.

We were told environmental risk assessments were performed by an external company and were not available to be seen on the day of the inspection.

We were told that Basic Life Support training was carried out by the registered manager, however, they had not been formally trained by the Resuscitation Council to deliver such training.

Infection prevention and control (IPC) and decontamination

Our observations of the reception area found the environment to be visibly clean and tidy. Corridors and walkways were clean and free from clutter. The premises was in a good state of repair which allowed for adequate cleaning.

We saw that the treatment beds were visibly clean and we were told that they were cleaned in between each patient. We were told that cleaning schedules for each theatre were stored behind the reception desk to prevent contamination.

A suitable waste disposal contract was in place for removal of clinical and sharps waste. We saw that the clinic had an IPC policy in place, this was accessed through their online database. Hand sanitiser was available throughout the clinic and disposable face masks were also available for patients and staff as required.

We found the clinical area was not visibly clean. We saw adhesive residue on trollies and surfaces. We saw surface dust on areas around the surgeries. The surgical theatre was not conducive of a sterile environment required for the procedures undertaken.

We saw the decontamination process was not sufficient for the procedures completed at the clinic. Reusable surgical instruments were decontaminated on site by the clinic staff. The process did not align with current best practice. We recommended that the decontamination of instruments was outsourced to ensure items were effectively sterilised.

These issues of cleanliness and IPC were dealt with under HIW's non-compliance process and are referred to in <u>Appendix B and Appendix C</u> of this report.

During the follow up inspection in September 2023 we saw an improvement in the cleanliness of the theatres. Soiled trolleys and surfaces had been replaced with new equipment that allowed for adequate cleaning.

We noted that a new ventilation system had been installed that provided air changes. We received assurance that these would be used according to the manufacturers guidelines.

Safeguarding children and safeguarding vulnerable adults

The service is registered to treat patients over the age of 18 years old. Our conversations with staff confirmed that this condition was complied with.

There was a safeguarding policy in place which was dated within the last year and included details of local safeguarding contact numbers and a safeguarding flowchart. The registered manager was the allocated safeguarding lead for the clinic. We were told that no safeguarding referrals had been made however staff were aware of the process to follow in the event of a safeguarding concern.

During our review of training records we saw staff had completed training in adult and child safeguarding.

Medical devices, equipment and diagnostic systems

The service was registered to provide cosmetic surgery according to their statement of purpose. We found the medical devices used by the clinic to be adequate for the services it provided. We saw evidence that machines had been serviced and calibrated recently by the manufacturer.

Service records for the medical machines at the clinic were up to date and had been completed by the supplier and the registered manager confirmed that relevant checks on the machines and equipment were undertaken prior to appointments.

Safe and clinically effective care

We reviewed the process by which patients were assessed before, during and after surgery. We were not assured that the existing process was sufficient to recognise a deteriorating patient. We were not assured that the monitoring of patients during procedures was sufficient to identify deterioration.

The registered manager explained the process in which patients can access assistance post operatively. We were told that the clinic is open for seven days each month and therefore is unstaffed for the majority of the month if patients require medical attention post operatively. If patients had a post operative problem they were advised to call a help centre based in Scotland who would then either advise the patient attend an Accident and Emergency department or request that a surgeon contact them and if required will travel to assess the patient.

We did not find this process a safe or adequate way to provide aftercare in the event of a post operative problem.

This issue was dealt with under HIW's non-compliance and is referred to in Appendix B of this report.

During our follow up visit, we were shown an improved process in which patients received vital sign recordings very 15 minutes during their procedure and this was overseen by a qualified clinician.

During our follow-up inspection the registered manager explained the reviewed system for post operative care. We were assured that the updated process for accessing medical advice was safe and sufficient.

Records management

Patient records were held and accessed via a secure online software which required a password to prevent unauthorised access. This was unique to each staff member. We were told that access to patient records were limited to clinical and

managerial staff. This system was used by all branches of Signature Clinic and so patient records can be accessed remotely if needed.

We saw that patients were asked to provide consent to photographs of their treatment progress. Photographs were stored securely within the same records system.

Quality of Management and Leadership

Governance and accountability framework

Signature clinic is operated by a registered manager who is also a joint owner of the company. We were told the registered manager visits the site once a month.. We saw that staff meetings took place monthly where information about the clinic was shared and discussed.

Overall, we found the clinics governance and leadership to be well structured with a clear organisational structure that covered several clinics across the country. The registered manager oversees all governance processes and is assisted by the human resources (HR) manager. Our review of staff records showed the HR manager had a well organised system in place to monitor staff training, appraisals and employment checks.

Dealing with concerns and managing incidents

We saw that concerns and incidents are logged in computer files and investigated by the registered manager. The clinic had a written complaints policy. This was available within the statement of purpose. To assist patients in making a complaint once they had left the clinic should they wish, we would recommend adding the complaints procedure and statement of purpose to the comprehensive clinic website.

We were told that any complaints would be dealt with promptly by the registered manager in the first instance whenever possible. We saw that several complaints had been saved within a documentation folder at the clinic. We were told that complaints received were mainly related to patients dissatisfied with the results of their procedures.

The registered manager told us that informal complaints raised verbally to a member of staff would be requested to be made in writing to ensure an appropriate response.

Workforce planning, training and organisational development

The registered manager explained that the clinic opens seven days each month and these days are chosen depending on demand.

The clinic staff were not based locally and travelled from the Birmingham branch. The human resources manager showed us an online database of training records and employment checks for these staff members. This system included diary makers and alerts to notify when training was due to be renewed.

Workforce recruitment and employment practices

We found that staff employed at the clinic and assisted during surgical procedures were not suitably qualified. We were not assured that these staff had the correct training and skills to provide patient care.

This issue was dealt with under HIW's non-compliance and is referred to in Appendix B of this report.

During the follow up inspection we have received evidence of newly appointed qualified staff. The updated staffing model was reviewed and accepted. The registered manager also appointed a clinic manager who was also a registered nurse to oversee the day-to-day management of the clinic and manage governance and safety.

We were provided with evidence of governance and safety meetings that were instigated, because of the inspection in order to further improve processes at the clinic.

4. Next steps

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

Appendix A - Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns Identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were resolved during the inspection			

Appendix B - Immediate improvement plan

Service: Signature Clinic, Cardiff

Date of inspection: 17 July 2023

The table below includes any immediate non-compliance concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
The registered person must employ suitably qualified staff who are skilled and experienced in surgical procedures.	Regulation 20(1)(a) of the Independent Healthcare Regulations Wales	Service has amended its theatre staffing policy and brought this in line with the Perioperative Care Council's position statement in 2019. The policy outlines the roles and defines what each role requires and can carry out in line with national best practice guidelines. Only NMC/ HCPC registered practitioners will carry out scrub duties going forward. A CV of the ODP recruited has been attached to this action plan.	Sayani Sainudeen	Policy in effect from 1 st August - completed ODP in post - completed
The registered manager must ensure all soiled equipment is removed from the theatres and that monitoring and emergency drugs and resuscitation equipment is available inside the theatre. In addition, the registered manager must	Regulation 40(1)(a) of The Independent Healthcare Regulations 2011	All soiled equipment removed and replaced. Infection Control nurse Jenny Gartland started 1 st Sept 2023.	Sayani Sainudeen	Soiled equipment replaced - completed Monitoring equipment has been in place

ensure that suitable ventilation is installed in the theatres.		Group Theatre Nurse - Lee Rycroft in place since 1st August 2023 Monitoring equipment is available in both theatres and both recovery rooms. A further PAT test has been carried out 05/09/2023 by electrical firm. Resuscitation Trolleys replaced with stocked Green Emergency Grab bags. One in each theatre. Ventilation units from Medicair installed in Theatre 1. We only plan to use a single theatre going forward.		Emergency drugs and resus trolleys replaced with BOC Green bags for emergencies Infection control nurse and Group Theatre Manager in place- completed PAT Testing carried out 05/09/2023 Ventilation units in place since 01/09/2023
The registered manager must ensure patients are monitored during their procedure and ensure that staff are able to recognise a deteriorating patient at the earliest opportunity. The registered manager must also put in place an aftercare process where patients are able to access medical advice or assistance both during and outside of normal operating hours.	Regulation 40(1)(d)(ii) and (iv) of The Independent Healthcare Regulations 2011	NEWS2 chart and intra-operative monitoring has been in place prior to the inspection date. This will continue with intra-operative observations being taken every 15 mins. An after-care policy has been put into place for the Cardiff clinic. The policy outlines a Level 1, Level 2 and Level 3 response for delivering aftercare in the event of the clinic being closed. Level 1 would be a 999 response. Level 2 would be to be see by a doctor in Cardiff within 24 hours.	Sayani Sainudeen and Valerie Taylor for training and policy creation Paul Macbeth working on the SLA agreements	NEWS 2 monitoring is in place Val to create a policy on management of deteriorating patient and a Transfer out policy by 10/08/2023 Val to train HCAs week commencing14/08/2023

	Level 3 would be a review by a surgeon at next visit within 3 weeks.	Meeting to extend aftercare by 08/08/2023
	Policy on deteriorating patient and a Transfer out policy is in place.	SLA with local private - GP SLA with University Hospital Wales - TBC depending on response from NHS which can vary

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative: Sayani Sainudeen

Job role: Medical Director and Registered Manager

Date: 06/09/2023

Appendix C - Improvement plan

Service: Signature Clinic, Cardiff,

Date of inspection: 17 July and 7 September 2023

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
The registered manager must ensure resuscitation training is performed by a suitably qualified individual.	Regulation 21(2)(b) of The Independent Health Care (Wales) Regulations 2011	Qualified BLS trainer employed and responsible to train all employees within the organisation	Valerie Taylor	Completed
Decontamination		No onsite sterilisation services in clinic. All surgery trays and instruments are decontaminated off site by a specialist decontamination services provider. Some disposable single use instruments are used.	Valerie Taylor	Completed

Complaints management	3 stage complaint policy (policy: Corp 01) (validated through clinical governance) is in place. Patient complaint information displayed in clinic, this poster includes HIW contact details	Valerie Taylor	Completed
Safe management of keys	Cupboards are locked and keys are held securely when clinic is closed. Keys are assigned daily to a registered healthcare professional (Registered Nurse or HCPC), log of signing in and signing out of keys is in place.	Valerie Taylor	Completed
Clinic manager	Registered healthcare professional (Registered Nurse or HCPC) manager on site as supernumerary staff at all times.	Valerie Taylor	Completed
Health protection and improvement	Health protection and improvement documentation has been developed to be provided to patients at pre-op stage, patients are provided with information and signposting to	Valerie Taylor	30/06/2024

	smoking cessation support. Patients will also be provided with information on healthy eating to aid wound healing and good hydration information to support wellness.		
IPC standards	Infection Prevention and Control Nurse Manager is in post. Infection Control audits conducted quarterly. IPC policies are in place.	Valerie Taylor	Completed
Welsh language availability	Interpreter service available in real time for any patient for whom English is not their first language, or if Welsh is their preferred language.	Valerie Taylor	Completed
Patient feedback	Patient feedback is requested at the 1 st post op call made by the aftercare team. Feedback is requested from all patients.	Valerie Taylor	Completed
Monitoring deteriorating patients	Staff are trained in Basic Life Support. Management of a	Valerie Taylor	Completed

	deteriorating patient policy is in place (policy CO14)
Aftercare provision	When the clinic is not scheduled to be open, an employed registered Healthcare professional (Registered Nurse or HCPC) is available to attend clinic on any day to open the clinic and provide follow up care.

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print): Valerie Taylor

Job role: Director of Clinical Services

Date: 17/06/2024