Refresh SouthWest Limited

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Overall summary

Refresh South West Limited is a private clininc in Plymouth, Devon providing various cosmetic proceedures for private patitents, for example the bodytight/facetight procedure. The clinic is owned and operated by Nicola Trathen, who is also the registered manager. The clinic primarily serves the communities of Devon though also accepts patient referrals from outside this area.

We carried out an unannounced focused inspection in response to concerns raised. We inspected this service as a focussed, unannounced inspection on 27 March 2018. We looked at the domains of safe and well-led in response to concerns raised and arising from our ongoing monitoring/intelligence about the service

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate. As this was an unannounced inspection responding to concerns we focussed on two domains, safe and well led.

At the inspection, we reviewed five patient records, three personel files, observed premises, interviewed two staff, and spoke with the registered manager.

Services we do not rate

We regulate cosmetic surgery services but we do not currently have a legal duty to **rate** them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following issues that the service provider needs to improve:

- The registered manager was unfamiliar with the requirements and their responsibilities with regards to the Health and Social Care Act 2008 (Regulated Activities) 2014.
- There was no mandatory training undertaken by staff working at the clinic.
- There were no procedures or processes to make sure people were protected from abuse. There was no scrutiny or oversight of safeguarding and staff had not received any safeguarding training.
- Infection prevention and control risks had not been considered. There was no routine of decontamination or cleaning.

Summary of findings

- There were no systems to monitor infection, prevention and control to ensure the premesis, including the operating theatre was clean and safe for use.
- The emergency equipment was not fit for purpose. There was no evidence that checks or servicing had been carried out for the anaphylaxis kit or defibrillator. The defibrillator was found to be indicating a battery replacement was required which meant we could not be assured it would work effectively.
- There were no systems or processes to enable the registered manager to monitor the safety, quality or performance of the service. The registered manager could not provide any assurance that the Health and Social Care Act was being adhered to.
- Risk assessments and associated management plans were not documented to give an account of the decision making process to safely manage the risk to patients.
- There were no processes to assess, monitor and mitigate the risks relating to the service.
- The service did not have adequate governance systems to protect patients attending the clinic. There was no formal governance framework to evidence and support the delivery of good quality care.
- There was a lack of oversight, audit, and assessment of the service provided. The lack of governance structure, systems or processes meant concerns and issues were not routinely identified and services could not be improved as a result. The lack of regard for following policy and procedure put both patients and staff at risk.
- There was no evidence to demonstrate the clinic assessed all patients to ensure their psychological wellbeing was considered in line with the Royal College of Surgeons recommendations for cosmetic surgery.
- Systems and processes did not ensure staff received appropriate pre-employment checks. There were no references or declarations under the rehabilitation of offenders act.
- There was no evidence to assure the registered manager that staff practice complied with policies.
- There was no system to provide assurance of staff competency.
- Patient records containing sensitive patient identifiable information were not stored securely.

However,

- Patient records were legible, concise and in order. We found completed consent forms, procedural notes and discharge summaries.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements to help the service improve. Full information about our regulatory response to the concerns we have described will be added to a final version of this report, which we will publish in due course.

Amanda Stanford

Deputy Chief Inspector of Hospitals (South West)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery		We do not currently have a legal duty to rate cosmetic surgery services. Surgical services at the clinic did not keep people safe from avoidable harm. There was no risk register or risk management system to identify, record, manage or mitigate risks. There were no systems and processes to keep patients safe from abuse or avoidable harm. There was an assumption safeguarding training was completed as part of other employment by staff coming to work with Refresh South West. We found issues with cleanliness and there were no systems or processes to prevent the spread of infection. The theatre scrub room was visibly dirty and had cleaning products on the walls and floor. We asked how the provider was assured that the cleaning was taking place and they were unable to tell us. Staff employed by the service did not have the right skills or qualifications to undertake to roles expected of them. A safe recruitment procedure was not in place to safeguard patients against unsuitable staff During the inspection we had concerns the registered manager did not understand her role and responsibilities in relation to the Health and Social Care Act 2008 (Regulated Activities) 2014. There was no evidence to demonstrate how the requirements of the act were being met by the provider. There was no evidence to demonstrate the clinic assessed all patients to ensure their psychological wellbeing was considered in line with the Royal College of Surgeons recommendations for cosmetic surgery. There was no governance framework to evidence and support the delivery of good quality care. There were no systems or processes which enabled the registered manager to monitor the safety, quality or performance of the service and identify areas which required improvement. There was a lack of oversight, audit, and assessment of the service provided. The lack of governance structure, systems or processes meant concerns and issues were not routinely identified and services could

Summary of findings

not be improved as a result. The lack of regard for following policy and procedure put both patients and staff at risk which would usually identified through a detailed assessment and monitoring processes.
All three personel files reviewed were incomplete and we could not be assured of an effective recruitment and selection procedure. For staff working for Refresh South West and for the regulated activity, the provider could not assure themselves that all checks were complete and satisfactory.
We reviewed three staff files and there were no processes to ensure staff were 'fit and proper' to provide care and treatment appropriate to their role and to enable them to provide the regulated activity. There were no effective recruitment procedures or ongoing monitoring of staff.

Summary of findings

Contents

Refresh South West Limited

Services we looked at
Surgery

Summary of this inspection

Background to Refresh SouthWest Limited

Refresh South West Limited is a private clinic in Plymouth, Devon providing various cosmetic procedures for private patients, for example the bodytight/facetight procedure. The clinic is owned and operated by Nicola Trathen, who is also the registered manager. The clinic primarily serves the communities of Devon though also accepts patient referrals from outside this area.

The clinic has an operating theatre, two treatment rooms, and a reception area. There are also consulting and administration rooms. There are no inpatient beds at the clinic. No surgical procedures are carried out on young people under the age of 18.

The regulated activity, the body tight/ face tight procedure forms only a small proportion of activity through the clinic. At the time of inspection we were told the clinic had performed 10 procedures in the last year. The clinic also offers cosmetic procedures such as dermal fillers, laser hair removal, and complementary therapies. We did not inspect these services as these procedures do not fall under our scope of registration.

The clinic has had a registered manager in post since 2010. The provider is registered to provide the following regulated activity:

Treatment of disease disorder or injury

Surgical procedures

Diagnostic and screening procedures

Our inspection team

The inspection team comprised of two CQC inspectors. The inspection team was overseen by Mary Cridge, Head of Hospital Inspection and Julie Foster Inspection Manager.

Information about Refresh SouthWest Limited

During the inspection we visited Refresh South West's only clinic. We spoke with the registered manager, two members of staff including a volunteer and a member of staff involved in marketing for the service. We also reviewed five patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service had previously been inspected in March 2014.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate cosmetic surgery services when they are provided as a single specialty service

We found the following issues:

- There were no systems or processes to ensure infection prevention and control regulations and standards were adhered to.
- Infection prevention and control risks had not been considered and managed appropriately.
- Risk assessments and associated management plans were not documented to give an account of the decision making process to safely manage the risk to patients.
- The registered manager was unable to define the duty of candour and their responsibilities to meet the requirements of this regulation.
- The registered manager was unable to demonstrate an understanding of their responsibilities under the health and social care act, including legal requirements.
- Staff had not undertaken any mandatory training.
- There were no systems or processes to assess, monitor or improve the quality and safety of the services provided.
- There was no risk register or risk management system to identify, record, manage or mitigate risks
- There were no internal or clinical audits for the regulated activity.
- The registered manager could not demonstrate their recruitment procedure ensured that staff working for the organisation were honest, reliable, trustworthy and respected or had the appropriate qualifications, skills and experience for the role they were undertaking.
- All files reviewed were incomplete and we could not be assured of an effective recruitment and selection procedures.
- The registered manager was unable to provide their own personnel file to assure us of any in date certification.
- The emergency equipment was not fit for purpose. No checks or servicing had been carried out for the anaphylaxis kit or defibrillator. The defibrillator was found to be depleted of charge which meant we could not be assured it would work effectively.

Summary of this inspection

- The registered manager could not assure us the equipment which the doctor used was suitable or sufficient. We were not provided with any evidence the equipment was cleaned or serviced in line with manufacturer's recommendations.
- Patient records were not stored securely. We found patient files stored on a shelf in the consultation room.
- The registered manager kept no records of the medications used by the attending doctor. We could not be assured that the registered manager had oversight that medication was stored or handled correctly.

Are services effective?

As this was a focussed unannounced inspection we did not inspect this domain

Are services caring?

As this was a focussed unannounced inspection we did not inspect this domain

Are services responsive?

As this was a focussed unannounced inspection we did not inspect this domain

Are services well-led?

We do not currently have a legal duty to rate cosmetic surgery services when they are provided as a single specialty service

We found the following issues:

- There were no systems or processes to enable the registered manager to monitor the safety, quality or performance of the service.
- There was no documented evidence to demonstrate how the service was being monitored to ensure it was providing a safe service.
- There was no formal governance framework to evidence and support the delivery of good quality care.
- There were no processes to assess, monitor and mitigate the risks relating to the service.
- There was a lack of oversight, audit, and assessment of the service provided to identify areas for improvement.
- The registered manager could not evidence compliance against policies and provide assurance to demonstrate staff were competent to carry out their role.

Surgery

Safe	
Well-led	

Are surgery services safe?

Incidents

- There was no incident reporting system or process and no encouragement for staff to report or investigate incidents or near misses. The registered manager was unable to tell us how incidents would be reviewed and managed other than they would be written in the accident book. The provider told us there had been no reported incidents within the last year. This meant there was a potential risk staff were not actively reporting incidents or near misses. We were not assured that incidents would be managed and investigated appropriately. There was no database or system to record incidents. As a result, we were unable to determine the track record on safety, whether incidents had been investigated or whether lessons were learned and improvements made when things went wrong.
- An absence of incident reporting meant the service was unable to measure safety performance over time. No safety goals had been set.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 duty of candour was introduced in November 2014. This Regulation requires organisations to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or could suffer harm that falls into defined thresholds. Despite prompting, when questioned, the registered manager was unable to clearly define duty of candour or their responsibilities to meet this regulation.

Clinical Quality Dashboard or equivalent (how does the service monitor safety and use results)

- There was no clinical quality dashboard or equivalent system to monitor safety performance. This meant the provider was unable to identify areas of strength or areas of the service which required improvement.

Cleanliness, infection control and hygiene

- There was a lack of evidence to demonstrate compliance with infection prevention control standards. Staff had not received training in infection prevention and control and there were no audits undertaken in respect of standards, such as hand hygiene or clinic cleanliness.
- The clinic had an infection control policy; however the lack of cleaning schedules, audits or staff trained in infection prevention and control indicated they were not following their own policy. The policy stated "records of cleaning should be maintained in accordance with the HCAI" (healthcare associated infections) guidelines. The registered manager was unable to provide these when requested.
- We were told during inspection that the treatment room had been cleaned over the weekend. However during the inspection, the scrub room was found to be contaminated with spilt cleaning products over the floor and walls.
- It was unclear who was responsible for cleaning as there had been recent staff changes and responsibility for cleaning had yet to be allocated. We were told prior to this, the provider had used tick sheets to monitor day to day cleaning, however, there was no evidence of this.
- The manager told us they did not routinely screen patients for infection as there was minimal risk within cosmetic surgery. Patients were prescribed antibiotic prophylaxis by the doctor performing the procedure.

Environment and equipment

- The lack of maintenance of equipment did not ensure the safety of patients. Equipment was not serviced or maintained as recommended by the manufacturer. There was no evidence that checks or servicing had been carried out for the anaphylaxis kit or defibrillator. The defibrillator was found to be indicating a battery replacement was required which meant we could not be assured it would work effectively.
- The provider did not maintain records regarding equipment checks carried out at the clinic. Daily or

pre-operative checks were not conducted or documented to ensure equipment was working or in service date. We were told this used to happen but lately due to staffing issues this had slipped.

- The registered manager could not assure us the equipment which the doctor brought with him and used was suitable or sufficient. We were not provided with any evidence the equipment was cleaned or serviced in line with manufacturer's recommendations.
- Clinical waste was not managed safely. We found two bags of clinical waste on the floor in a side room, known as the dirty room, along with two full sharp bins. We were told these were removed by a local certificated disposal company. We were not assured this waste was collected regularly. There were only two invoices available to evidence the collection of clinical waste which were from 2017. The service had performed procedures in 2018 but could not account how they had disposed of the contaminated waste.
- Fire-fighting equipment had been maintained and tested by an external company.
- All surgical instruments were single use disposable items. This helped minimise the risk of infections.

Medicines

- At the time of our inspection we were not assured the manager had sufficient oversight of the processes surrounding the purchase, storage and handling of medication. Subsequently we were told that medicines and their records were stored securely in theatre although this was not seen at the time of the inspection.
- There was an anaphylaxis kit available if a patient suffered an allergic reaction. However, routine checks were not carried out to monitor expiry dates.
- Allergies were clearly documented. In the patient files we looked at, we saw that allergies were discussed and recorded on the patients' notes.

Records

- Patient care records were completed for all patients receiving care and treatment. We looked at a sample of five patient records. We found these were legible and provided a clear account of the patient's allergies, side effects related to the procedure, consent and other procedural notes.
- However, not all records were stored securely. We found some records stored on a shelf in the consultation room which contained patient sensitive information. We were told they were being sorted for a financial accountant. However, on the day of the inspection two other members of staff were present. Both of these staff had access to these records containing patient sensitive data.

Safeguarding

- There were no systems and processes to keep patients safe from abuse or avoidable harm. The lack of safeguarding procedures was in part linked to the issues found in mandatory training section below. There was an assumption safeguarding training was completed as part of other employment by staff coming to work with Refresh South West. We could not be assured staff had a suitable level of safeguarding adults training. This posed a risk staff were not up to date to enable them to recognise different types of abuse and the ways they could report concerns.
- The recruitment procedure did not safeguard patients against unsuitable staff. We found staff files did not contain the required information to meet the legal requirements, including Schedule 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- The registered manager identified themselves as the safeguarding lead. However they could not evidence their current training level in safeguarding. Therefore we could not be assured they would be able to recognise safeguarding issues in vulnerable patients.

Mandatory training

- Staff did not receive mandatory training in safe systems, processes or practices. The provider was unable to show compliance with mandatory training. There was no training oversight to determine the qualifications, level and frequency of training required for each staff role. This meant staff were not up to date with training to ensure they were caring out aspects of their role safely.
- The registered manager told us there was an assumption staff undertook relevant training with their main employer as a clinician and therefore no internal training was provided. There were no established systems to seek assurance or evidence from staff or their employers to demonstrate staff were up to date with their mandatory training.

- The registered manager was unable to provide evidence they had completed mandatory training. They told us they had completed their first aid training last year by a company called "Resus South west." Following the inspection, we looked into this company. The company had, according to companies' house, been dissolved since 2015
- We were told some staff were due to sit an infection, prevention and control course soon. At the time of inspection, none had any current evidenced training.

Assessing and responding to patient risk (theatres, ward care and post-operative care)

- A limited risk assessment was completed for patients choosing to undergo procedures at the clinic. This took into account allergies and any other past medical history such as complications from surgery.
- There was no evidence to demonstrate the clinic assessed all patients to ensure their psychological wellbeing was considered in line with the Royal College of Surgeons recommendations for cosmetic surgery. There was no record that psychological concerns of patients undergoing the cosmetic procedure were discussed. We could therefore not be assured people suffering from body dysmorphia or other similar psychological conditions were being assessed as to their suitability for surgery. It is a requirement of the Royal College of Surgeons this key aspect of consultation identifies any patients who are psychologically vulnerable and they are appropriately referred on for further assessment.
- The internationally recognised five steps to safer surgery, World Health Organisation (WHO) surgical checklist was used to ensure patient safety throughout the patient journey. The checklist formed part of a process carried out to scrutinise all safety elements of a patient's operation/procedure before and after. This included, for example, checking it was the correct patient, the correct operating site, consent had been given, and all the staff were clear in their roles and responsibilities. The patient records we reviewed demonstrated this had been used. However there was no audit process to ensure that this procedure was followed every time a patient had surgery.
- In the event of a patient becoming acutely unwell before, during, or after a procedure, the registered manager told us their immediate course of action would be to administer emergency first aid and then call 999, if appropriate. However we were not assured that staff were adequately trained to due to the lack of mandatory training recorded within their personnel files.
- Patients were offered support after surgery. Both the registered manager and doctor made post procedural phone calls. Patients could also access the doctor when required following surgery. Patients were given information on what side effects to expect after surgery and contact information for the doctor should they have any concerns.

Nursing and support staffing

- Staffing was planned and rostered to ensure appropriate levels to meet patients' care and treatment needs. However, we were not assured of staff competency at recruitment and on an on-going basis to provide safe care and treatment.
- The provider had one band five nurse employed on a freelance basis when required. However we were not assured of this nurses registration to the Nursing and Midwifery council as the registered manager had an incomplete personnel file for this member of staff. The Disclosure and Barring Service (DBS) certificate was incorrect and showed the member of staff as a health care assistant. The registered provider used the term 'nurse' without understanding the role and its responsibilities and was not clear at inspection of the skills required for the theatre nurse role. The registered manager could not provide assurance that the staff in post had the skills needed to undertake the roles expected of them. There was no research to establish the skills needed for the role and no assessment of skills or competence recorded to unsure the staff member was appropriate.
- We found no offers of employment or contracts, it was not clear if staff employed had received the relevant checks. Gaps included no references, no evidence of DBS and voluntary staff who was employed in an ad hoc capacity to do day to day tasks around the clinic, yet they were exposed to clients on arrival to the clinic

Medical staffing

- A visiting doctor came to perform the regulated activity when required by Refresh South West. When patients requested the procedure the registered manager

booked all necessary staff to be available for the date required. The doctor worked on a contractual basis and there were no records of current revalidation, appraisal or insurance cover kept on site.

- The registered manager was not aware of practicing privileges required for doctors attending the clinic to preform services under the regulated activity. This meant the provider could not be assured that the doctor was registered as a medical professional with or General Medical Council.

Emergency awareness and training

- There were no business contingency plans for the provider. We were told that the procedure would be postponed if the power went mid-procedure. As patients were conscious and not sedated. If there was a loss to power the procedure would be halted and there would not be a risk to patient safety.

Are surgery services well-led?

Leadership / culture of service related to this core service

- Leaders did not have the skills or knowledge to ensure they were delivering safe care. The registered manager was not aware of their responsibilities under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- The registered manager did not ensure that employees who were involved in invasive procedures were supported or educated in good safety practice. The registered manager had limited evidence staff working at the clinic were qualified and competent to carry out their roles.
- A lack of oversight and assurances meant the leaders of this business were unaware of staff prior backgrounds or competencies. Additionally safe systems were not embedded to ensure that checks on premises or equipment were being done.
- Leaders did not understand the challenges to ensure good quality care due to a lack of governance and audit processes. Therefore they were unable to identify actions and address them in timely manner.
- The registered manager was visible to staff during the week. However during the weekends when the regulated activity was taking place, the registered manager was not on site.

Vision and strategy for this core service

- There was no formalised vision or strategy for the service provided by Refresh South West. As this was a private company the registered manager identified the priorities and the direction of the organisatioin, taking into accountfinancial considerations.. The registered manager said they would approachtheir business partners for advice in their specialist areas and would then make any changes required.

Governance, risk management and quality measurement

- There was no governance framework to evidence and support the delivery of good quality care. The service had no systems or processes to monitor the safety, quality or performance of the service The registered manager told us discussions occurred occasionally about the business with a partner but these were informal and not documented. There were no formal meetings to discuss the service and its performance.
  - There was no programme of audit to identify how the service was performing. Safety, quality and activity information was not regularly captured to enable the provider to understand how the service was performing to identify areas for improvement. Lack of audits meant they were unable to benchmark their performance against similar services. the service had no means of monitotring complication rates or patient outcomes.
  - The provider recognised they could not evidence compliance against policies or provide assurances of staff competency. For example, the provider was unable to produce requested information relating to a nurse employed by the service..
  - There was no organised system for the provider to store documents, for example policies, procedures, recruitment checklists or audits. We found this information was not available or accessible when requested as they were stored in different locations around the clinic. For example, patient records which should be readily available took some time to find amongst other documentation.

- The provider did not have a formal risk register or any other system to effectively record and manage risks. A risk register is a management tool, which enables an organisation to understand its risk profile, as risks are logged on the register and action taken to respond to the risks. This meant that they were unable to notice trends in incidents and put systems in place to lower any risks to patients, premises or the business.

Public and staff engagement (local and service level if this is the main core service)

- There was limited feedback collected from patients. We were shown evidence of questions asked of patients following a procedure. Some of this information was dated, we found others that were not dated. The last date we saw for collected feedback was from 2016. We were therefore not assured the patient's voice was soughtand taken into account when planning and delivering services.
- There was no formal system for gathering staff feedback. Staff feedback was not actively sought or recorded. Despite this, the registered manager felt staff were confident to raise concerns or feedback issues if they felt they needed to.

Innovation, improvement and sustainability (local and service level if this is the main core service)

- The registered manager told us they had regular unminuted meetings with the business partner but was unable to describe any future plans for innovation, improvement and sustainability.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The registered manager must demonstrate that they have the appropriate knowledge of applicable legislation including the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and understand the consequences of failing to take action on set requirements.
- Take prompt action to ensure understanding of the duty of candour regulation, including roles and responsibilities with regards to its application and to have a system that ensures its completion .
- Implement an effective governance framework to support and monitor the delivery of good quality and safe care.
- Ensure processes to assess, monitor and mitigate risks relating to the health, safety and welfare of patients and others who may be at risk are established.
- Ensure all clinical waste is managed in line with national guidance and legislation.
- Ensure staff are competent and experienced to provide safe care and treatment relevant to their role, and be able to evidence this.
- Ensure recruitment procedures meet the requirements of the Health and Social Care Act 2008
- Have effective systems to monitor and provide assurance of compliance with standards in relation to infection prevention and control.
- Establish a process for reviewing equipment, particularly emergency equipment, to confirm it has been checked, is in date and suitable for use.
- Ensure all staff have the required mandatory training in order to carry out their role.
- Ensure all staff have safeguarding training at the appropriate level.
- Ensure that all records are managed in such a way that confidentiality is maintained at all times.

Action the provider SHOULD take to improve

- Review all policy and procedure documents sothey are accurate and reflective of the processes required of the service.
- Check all policies and procedures are fully embedded into day-to-day practice.
- Review the document system for all staff and their mandatory training information to ensure this provides a clear oversight of compliance.