Re-Enhance Limited

Quality Report

Progress House
Cecil Road
Hale
WA15 9NZ
Tel:01619413212
Website:re-enhance.com

Date of inspection visit: 1 and 14 March 2017
Date of publication: 06/06/2017

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

Re-Enhance is operated by Re-Enhance Limited. The service offer cosmetic day case services for surgery, dental treatments and medicine services. Facilities include four treatment rooms and diagnostic facilities.

The service provides surgery, medicine and dental services. We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 1 March 2017, along with an unannounced visit to the service on 14 March 2017. We also visited the service's satellite location on 8 March 2017.

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.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The main service provided by this clinic was medicine. Where our findings on medicine – for example, management arrangements – also apply to other services, we do not repeat the information but cross-refer to the medicine core service.

We regulate cosmetic surgery services, but we do not currently have a legal duty to rate them. 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:

- Staff did not have current statutory training in key areas such as health and safety, manual handling, fire safety and infection control. Staff also did not have current safeguarding training.
- The system to learn from and make improvements following any accidents, incidents or significant events required improvement.
- The clinic did not have any standard operating procedures for bio-identical hormones and did not reference applicable guidance.

Summary of findings

- Whilst patients' needs were assessed and their care was planned and delivered in line with the clinical lead's range of course guidance materials, patients' records did not demonstrate how the clinic complied with these standards and how decisions were made.
- At the time of our inspection, audits were not undertaken to monitor compliance with guidance and standards.
- At the time of our inspection, outcomes of people's care and treatment were not routinely collected and monitored.
- Patient records were not completed in line with the GMC guidance on good record keeping. They lacked evidence of comprehensive pre-assessment and clinical reasoning for decision-making was not contained within patients' medical records.
- There was no documented process for referring patients on to services such as counselling, if needed.
- The clinics complaints policy referenced the Local Government Ombudsman rather than the Independent Sector Complaints Adjudication Service (ISCAS). This showed that the service provided incorrect information as to who patients should raise concerns with.
- The provider did not have effective systems and processes in place to ensure there was appropriate governance and managerial oversight of the clinic.
- The provider did not have a clear governance framework and management could not evidence that they regularly reviewed the systems that were in place.
- There was not a comprehensive assurance system and service performance measures in place at the time of our inspection.
- The provider did not have arrangements in place to collate information to monitor and manage quality and performance.
- Not all staff that were registered with the General Dental Council (GDC) could provide evidence that met the requirements of their professional registration by carrying out regular training and continuing professional development (CPD).

However, we also found:

- Infection prevention and control procedures broadly followed nationally recognised guidance from the Department of Health. We saw instruments were placed in pouches after sterilisation but these were not dated to indicate when they should be reprocessed if left unused.
- Equipment for decontamination procedures, radiography and general dental procedures were tested and checked according to manufacturer's instructions.
- Emergency medicines were stored appropriately but some adjustments were necessary to comply with Resuscitation Council UK guidelines.
- Staff were aware of their responsibilities under the Duty of Candour.
- The premises and clinical areas were visibly clean at the time of our inspection.
- Equipment was appropriately tested and calibrated.
- In terms of dentistry, we found that this practice was providing effective care in accordance with the relevant regulations.
- Dental professionals referred to resources such as the National Institute for Health and Care Excellence (NICE) guidelines and the Delivering Better Oral Health toolkit (DBOH) to ensure their treatment followed current recommendations.
- Dental care records were kept securely on computer systems, which were password protected and backed up at regular intervals.
- Patients were treated with dignity, compassion and empathy.

Following this inspection, we issued a warning notice for the breach of four regulations under the Health and Social Care Act. We also told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though other regulations had not been breached, to help the service improve. We also issued the provider with requirement notices that affected medicine and surgery. Details are at the end of the report.

Ellen Armistead

Summary of findings

Deputy Chief Inspector of Hospitals

Summary of findings

Contents

Re-Enhance Limited

Services we looked at
Medical care; Surgery; Community dental services

Summary of this inspection

Background to Re-Enhance Limited

Re-Enhance is operated by Re-Enhance Limited. The service opened in 2010. It is a private clinic in Hale, Cheshire with a satellite location in Wakefield. The clinic primarily serves the communities in the Greater Manchester and Cheshire areas. It also accepts patients from outside this area. The clinic has had a registered manager in post since August 2012. The clinic also offers cosmetic procedures such as dermal fillers and laser hair removal. We did not inspect these services.

The regulated activities are:

Diagnostic and screening procedures

Surgical procedure and

Treatment of disease, disorder or injury

Following our inspection, we issued a warning notice for four regulatory breaches.

Our inspection team

The team that inspected the service comprised a CQC lead inspector,three other CQC inspectors and an inspection manager. The inspection team was overseen by Ann Ford, Head of Hospitals Inspection.

Information about Re-Enhance Limited

Re-Enhance offer a comprehensive range of treatments from the clinics. These include non-surgical cosmetic treatments, which were not regulated by us.

Re-Enhance also offer a bespoke range of anti-aging, preventative healthcare services such as food intolerance testing, blood testing and profiling, vitamin mineral and bio-identical hormone replacement. The service also provided dentistry services from their Hale location.

The clinic has four treatment rooms and is registered to provide the following regulated activities:

- Diagnostic and Screening procedures
- Surgical Procedures
- Treatment of disease, disorder or injury

During the inspection, we visited the Hale and Wakefield clinics. We spoke with nine staff including; a registered nurse, health and beauty therapists, trainee dental nurses, reception staff, medical staff and the registered manager. We spoke with nine patients and one relative.

We also received 21 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed 15 sets of patient records.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The clinic has been inspected twice, and the most recent inspection took place in July 2013, which found that the clinic was meeting all standards of quality and safety it was inspected against.

Activity (March 2016 to February 2017)

- In the reporting period 1 March 2016 to 1 February 2017 there were 534 medical appointments, 337 dental appointments and 9 surgical procedures undertaken. All treatment was provided on a private basis.

One dentist and one theatre nurse worked at the clinic under practising privileges. The service employed one clinical lead, who was also dual registered as a dentist, three health beauty therapists, one blood analyst/dental technician, two receptionists and a registered manager.

Summary of this inspection

Track record on safety

- No Never events
- No clinical incidents
- No serious injuries

No incidences of clinic acquired Methicillin-resistant Staphylococcus aureus (MRSA),

No incidences of clinic acquired Methicillin-sensitive staphylococcus aureus (MSSA)

No incidences of clinic acquired Clostridium difficile (c.diff)

No incidences of clinic acquired E-Coli

No complaints

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

- Patient records were not completed in line with the GMC guidance on good record keeping. They lacked evidence of comprehensive pre-assessment and clinical reasoning for decision-making was not contained within patients' medical records.
- Staff did not have current statutory training in key areas such as health and safety, manual handling, fire safety and infection control. Staff also did not have current safeguarding training.
- The system to learn from and make improvements following any accidents, incidents or significant events required improvement.
- The service was not undertaking six-monthly infection control assessments in line with the government Health Technical Memorandum (HTM 01-05).
- A risk assessment process for Legionella had not been carried out by the practice. We saw evidence that the water supply was tested annually for the presence of bacteria and had been within the accepted limits.
- We found dental and medical consumables and medication in the surgery that had passed their expiry date and staff including service leads were not aware of this.
- The clinical lead did not have current advanced life support (ALS) training and staff were not trained on the use of the resuscitation equipment.
- Trainee dental nurses were not familiar with recommended manual decontamination protocols.
- A risk management process had not been undertaken for the safe use of sharps (needles and sharp instruments.
- Records of Hepatitis B immunisation were not available and risk assessments had not been carried out on staff who were involved with exposure prone procedures but could not demonstrate immunity.
- The practice recruitment policy was not in line with requirements.

However, we also found:

Summary of this inspection

- Infection prevention and control procedures broadly followed nationally recognised guidance from the Department of Health. We saw instruments were placed in pouches after sterilisation but these were not dated to indicate when they should be reprocessed if left unused.
- Equipment for decontamination procedures, radiography and general dental procedures were tested and checked according to manufacturer's instructions.
- Emergency medicines were stored appropriately but some adjustments were necessary to comply with Resuscitation Council UK guidelines.
- Staff were aware of their responsibilities under the Duty of Candour.
- The premises and clinical areas were visibly clean at the time of our inspection.
- Equipment was appropriately tested and calibrated.

Are services effective?

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

- The clinic did not have any standard operating procedures for bio-identical hormone therapies and did not reference applicable guidance.
- Whilst patients' needs were assessed and their care was planned and delivered in line with the clinical lead's range of course guidance materials, patients' records did not demonstrate how the clinic complied with these standards and how decisions were made.
- At the time of our inspection, audits were not undertaken to monitor compliance with guidance and standards.
- At the time of our inspection, outcomes of people's care and treatment were not routinely collected and monitored.
- The service did not participate in relevant local and national audits or peer review exercises.
- Staff within the service and the registered manager confirmed that staff members did not have appraisals.
- The registered manager and clinical lead were not able to provide any written evidence of the monitoring of staff competency to undertake key aspects of their roles such as taking bloods and provision of intra-muscular injections.
- The service did not have documented clinical pathways, for the medical services provided in place at the time of our inspection.

Summary of this inspection

- The clinical lead told us they were unaware of the Professional Standards for Cosmetic Surgery provided by the Royal College of Surgeons (RCS). This meant there was a risk that patients were not receiving treatment in line with best practice guidance.
- Staff had not received MCA training and they did not demonstrate a good understanding of the MCA
- Not all staff who were registered with the General Dental Council (GDC) could not provide evidence that met the requirements of their professional registration by carrying out regular training and continuing professional development (CPD).

However, we also found :

- In terms of dentistry, we found that this practice was providing effective care in accordance with the relevant regulations.
- Dental professionals referred to resources such as the National Institute for Health and Care Excellence (NICE) guidelines and the Delivering Better Oral Health toolkit (DBOH) to ensure their treatment followed current recommendations.
- Dental care records were kept securely on computer systems, which were password protected and backed up at regular intervals.

Are services caring?

We found:

- Patients were treated with dignity, compassion and empathy.
- Patients we spoke to were positive about their experience and felt the staff got to know them on a personal level.
- Patients felt fully informed about their treatment and said they felt staff explained their treatment to them clearly.
- Patients felt they got the emotional support they needed throughout their treatment at the clinic.
- Privacy and confidentiality were maintained for patients using the service. We also observed staff to be welcoming and caring towards patients.

However, we also found:

- There was no documented process for referring patients on to services such as counselling, if needed.

Are services responsive?

We found:

Summary of this inspection

- Patients could book an appointment at a time that suited them and opt to use one of the clinics satellite sites if this was more convenient.
- Fees were discussed up front when patients booked appointments so patients were aware of the costs from the point of initial contact with the clinic.
- The practice had made reasonable adjustments to prevent inequality to any patient group. The treatment room was accessible to patients with limited mobility and wheelchair users but the toilet was not. The patient information leaflet included a disability access statement, which confirmed this clearly to patients.
- Staff could access an interpreter if required and there was space on the consent form for the interpreter to sign and date.

However, we also found the following issues that the service provider needs to improve:

- The clinics complaints policy referenced the Local Government Ombudsman rather than the Independent Sector Complaints Adjudication Service (ISCAS). This showed that the service provided incorrect information as to who they should raise concerns with.

Are services well-led?

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

- At the time of our inspection senior leaders within the clinic did not demonstrate a comprehensive awareness of the information they needed to manage the clinic.
- The provider did not have effective systems and processes in place to ensure there was appropriate governance and managerial oversight of the clinic.
- The provider did not have a clear governance framework and management could not evidence that they regularly reviewed the systems that were in place.
- There was not a comprehensive assurance system and service performance measures in place at the time of our inspection.
- The provider did not have arrangements in place to collate information to monitor and manage quality and performance.

However, we also found:

- The practice had systems in place to seek and act upon feedback from staff members and people using the service.
- The service had a clear vision and strategy in place, but this was not documented.

Summary of this inspection

- The ethos of the practice was clearly apparent in all staff as being able to provide the best service possible.

Medical care

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are medical care services safe?

Incidents

- There were no 'never events' reported in relation to the medical services at the clinic. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- The service had an 'Adverse events and near miss policy', which detailed the actions staff should take to report an incident and the escalation process to follow. The policy also outlined examples of what would constitute a clinical 'near miss'; however staff were not aware of the content of this policy. Staff were unaware of any documentation to report incidents.
- Staff told us they would inform the practice manager of any 'incidents'; however they were unaware whether an accident book was available to record accidents or if there was a process to investigate incidents. We were not assured staff knew how to identify and report an incident.
- Staff we spoke to were unsure about what would constitute an incident for reporting purposes.
- Staff were aware of their responsibilities under the Duty of Candour. Duty of candour is a requirement under The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 on a registered person who must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.
- Staff did not complete incident report forms when incidents occurred, for example, when the fridge temperatures went out of range and the fridge subsequently broke. This is against the clinic's health and safety policy. Therefore, the clinic management did not assess the risks to the health and safety of service users receiving care or treatment; and did not do all that was reasonably practicable to mitigate any such risks.

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

- The service did not use a clinical quality dashboard.
- The service did not have any documented evidence of how it monitored safety and used the results for learning. However, the registered manager and clinical lead advised us that the clinical lead had overall clinical responsibility and that the general day to day running of the clinic was the registered manager's responsibility.

Cleanliness, infection control and hygiene

- The clinic rooms and theatre area were visibly clean and tidy.
- The service had a cleaning schedule in place that covered all areas of the premises and detailed what and where equipment should be used. We could not see evidence of national guidance on colour coding equipment to prevent the risk of infection spreading, but staff told us that the cleaner brought their own cleaning products and supplies.
- Staff were not sure whether there was a spillage kit available to clear up any spillage of blood or body fluids. At the time of our inspection, we did not see evidence of the clinic stocking a spillage kit. Staff told us they would use bleach to clean up blood or body fluids.
- There was a generic written infection control policy, which included minimising the risk of blood-borne virus

transmission which included Hepatitis B. Senior managers undertook annual reviews of infection control and prevention standards.The government Health Technical Memorandum (HTM 01-05) stipulates that these reviews should be carried out minimally on a six monthly basis. Senior managers were unaware of this code.

- Senior managers had not arranged for legionella assessments for water sources within their premises to be undertaken. This meant that reliable systems were not in place to protect people from a healthcare acquired infection.
- There were no cases of Methicillin-resistant Staphylococcus aureus (MRSA) bacteraemia, Methicillin-sensitive Staphylococcus aureus (MSSA) bacteraemia, Clostridium difficile (C.diff) or Escherichia coli (E. coli) reported by the clinic. The clinic did not screen for these bacteraemia as part of the bio-identical hormone blood screening process.
- The clinic did not have a system in place to improve and review safety systems and processes.

Environment and equipment

- The theatre and treatment rooms were tidy and free of clutter.
- Resuscitation equipment and some emergency medicines were present at the time of the initial inspection; however the contents of the resuscitation trolley did not meet those recommended by the Resuscitation Council. The ambubag, glyceryl trinitrate spray, Salbutamol, dispersible aspirin, glucagon, buccal midazolam and spacer device were all missing. We escalated this issue to the provider as an immediate patient safety risk and when we returned the missing items had been ordered and the clinic was awaiting delivery of one outstanding medicine.
- At the time of our inspection the clinic could not evidence that any staff member had basic first aid training, basic life support training or advanced life support training. The registered manager told us that all staff, excluding the clinical lead, had not been trained in the use of the resuscitation trolley.
- There was an automated external defibrillator (AED).
- We saw records that showed the emergency medicines and equipment were checked on a daily check. Staff knew the location of the emergency equipment.
- There were a large number of expired consumables stored in trolleys and cupboards in the clinic, these included adhesive dressings with expiry dates ranging from 24 December 2008 to 12 June 2010, one box of mesobelle needles, one bag of transport swabs expiry date January 2011, six rolls of micropore tape, one box of spinal needles and 20 ampules of steripod water for injection. There were also packs of syringes, hand wipes and two trays of vacutainers for blood collection expiry October 2016 and December 2016.
- There were personal items stored alongside clinical consumables in a drawer and cupboard in clinic room four and the clinic storeroom.
- The service had an automated immunoassay machine on site, which was appropriately calibrated and maintained in line with the manufacturer's guidance.

Medicines

- There was a 'management of medicines policy' at the clinic. However, we found multiple breaches of the policy during our inspection, these included: the service not ensuring the safe storage and security of medicines, not recording delivery and collection of medicines and not reporting incidents involving medication, adverse drug reaction and the monitoring of emergency medication.
- Medications were not kept in locked cupboards or in locked clinic rooms, leaving them unsecure and allowing for unauthorised access. The clinic's policy states: 'Medicines are stored in a locked cupboard or controlled area' and our findings on inspection did not reflect this.
- Staff members stored their own medications alongside those prescribed to patients. Topical medications were stored on a racking shelf in the store room, which was not temperature controlled, therefore there was no way of verifying whether the medications were being stored in line with their storage instructions. The 'management of medicines policy' states medicines requiring refrigeration would be stored in a lockable fridge. The fridge was faulty and had been recording out of rang temperatures. This had not been reported as incident.

Medical care

- For prescribed medications, there was no record in the prescription book that the patient had collected their medication. The last date for collection of medication in the book was the 18 August 2015. However, the clinic had recorded that medication was ordered up until 9 March 2017. All collection dates between 18 August 2015 and 9 March 2017 were incomplete.
- Prescribed medication was not recorded as delivered in the prescription book. This was a breach of the clinic's 'management of medicines policy' under the ordering and receipt of medicines section.
- There was no procedure for controlled drugs. Controlled drugs were not stored appropriately and there was no controlled drug log book.
- There was no oversight for private prescriptions or audit of medication prescribed by the clinical lead.
- We found expired prescription medication for patients in a cupboard in a clinic room. This included Ceftriaxone solution injections (expiry January 2017) and an unidentified medicine. The medication had not been disposed of in line with the 'Management of medicines policy'. We raised this with the clinical lead and registered manager, who confirmed the unidentified medication had been brought in by a patient, for by the clinical lead, and should have been disposed of in line with the policy. When we returned on our unannounced inspection, the expired medication had been disposed of.
- We found expired medication in use at the clinic, this included: four vials of Somatropin (a human growth hormone), one box of Ceftriaxone, 17 vials of Hydroxocobalamin (Vitamin B12a) and 12 bottles of bacteriostatic saline. This was a risk to patient safety. We escalated this to the clinical lead and registered manager and they took action to remove the expired medications. The clinic did not have records of which patients may have been prescribed expired medications as the prescriptions were not routinely audited and batch numbers and expiry dates weren't recorded in the patients' records. This meant the clinic was unable to identify which patients had received a specific medication.
- There were patient records where the appropriate batch number of medications had not been recorded. This was a breach of the clinic's management of medicines policy and should have been reported as an incident, as the policy states.
- We were not assured whether the clinic had administered expired medication to patients, as batch numbers of medication given were not routinely recorded in patients' records. The clinic routinely administered Hydroxocobalamin (Vitamin B12a) injections, as part of the bio-identical hormone treatment, and a large quantity of this medication was found to be expired.
- Copies of private prescriptions were held in the patient records, but there were no comprehensive consultation or follow up notes to explain why the medication had been prescribed and whether it was an initial or repeat prescription.
- Hormone medication prescribed by the clinic was unlicensed. There was no prescribing criteria or standard operating process in place which is not in accordance with best practice.
- There were no documented audits of stocks of medication held. The clinic did not hold an inventory of the medicines held and there was no robust process to identify and dispose of expired medications. There was no clear guidance in the policy as to who was responsible for checking all medications for expiry dates. The policy referenced emergency medicines only.

Records

- Staff used paper based patient records and these were stored in lockable filing cabinets in the clinic.
- Records for patients who were booked in to clinic were kept behind the reception desk. There was no locked drawer or secure storage in the reception area for patients' files. Although the main door to the clinic was usually locked, reception was not continually manned, so records were unattended at times which had the potential to allow for unauthorised access.
- We looked at the records of six patients. We found there was a gap in the recording of consultations and medical history in patient records.

- The hormone medication prescribed to patients was unlicensed. There was no documented evidence that this had been discussed with patients or that consent had been sought to prescribe unlicensed medication. This was not in accordance with best practice as risks associated with unlicensed medications should be discussed to enable patients to make informed choices. Patients should also provide written consent to confirm they understand the risks and accept the risks in taking unlicensed medication.
- There was no documented evidence that fees had been discussed at the consultation, but a staff member we spoke to confirmed patients were given the information on fees when they booked in the appointment to see the clinical lead for a bio-identical hormone consultation.
- Patients' medical history in relation to bio-identical hormone treatment was filled in by the patient on a gender specific consultation form that was emailed once they had booked an appointment. There was space on the 'new patient pro-forma' for additional medical history notes, but there was no evidence that further history had been discussed with the clinical lead as these were not robustly completed in the records we reviewed. Consultations and follow up appointments were poorly documented and there were no further medical notes in the records.
- There was no documented evidence of basic patient information such as blood pressure or weight in the bio-idential hormone consultation records. The clinical records we reviewed did not document comprehensive pre-assessments and screening of patients to ensure that risks to the health, safety and welfare to service users were assessed, monitored and mitigated.
- Clinical reasoning for decision-making was not contained within the patients' medical records we reviewed. The clinical lead confirmed otherpatients' records were in line with the 15 records we had reviewed and would not evidence a complete and contemporaneous record being available for each service user that included a record of care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided. The absence of a record keeping audit meant the registered manager or service did not identify this issue.

Safeguarding

- The service had a safeguarding policy which outlined how to report safeguarding issues.
- The service had information on how to report safeguarding issues held in a policies folder at the clinic.
- No staff within the service had current safeguarding training. Staff in the service had received safeguarding training in 2013 (although the level could not be verified) but the training had expired in 2016 and had not been refreshed. The registered manager was not aware that this training needed to be refreshed every three years.
- The clinical lead did not have current adult or children's safeguarding training and advised he was unaware of the need to update this training.
- There were no safeguarding incidents reported by the clinic in the past 12 months.

Mandatory training

- The service had not provided current fire safety, manual handling and infection control training to its staff members. At the time of our inspection on 1 March 2017, there was no evidence staff had received this training in staff files and there was no training matrix or a subject list in place to stipulate what training was required for each staff member.
- We requested a list from the registered manager of what subjects were considered mandatory training and this list was not comprehensive and excluded key areas including moving and handling, infection control and the use of display screen equipment. The list supplied as mandatory training subjects comprised of: basic health and safety including COSHH, fire safety, safeguarding and laser safety core of knowledge for laser therapists.
- The certificates for staff training in health and safety were undated and were not accredited to an issuing authority or body. The registered manager confirmed to us that these certificates were over 12 months old and that there was not a set frequency for training to be repeated and/or updated. Therefore the service did not ensure that persons providing care or treatment to service users had the qualifications, competence, skills and experience to do so safely.

Medical care

- The provider did not have a comprehensive health and safety policy in place at the time of our inspection and the policy was not followed. The policy stated that staff will receive an annual update on moving and handling training. The registered manager told us that staff did not have moving and handling training, as it was not applicable to their role. Staff files confirmed that staff did not receive training in this area. The Manual Handling Operations Regulations 1992 do not exclude the clinic's staff from the application of these regulations and therefore staff should receive training in this area.
- Staff files did not evidence COSHH training, fire safety awareness training, basic risk assessment training nor any evidence of regular updates in essential areas including safeguarding training.

Assessing and responding to patient risk

- Patients had an initial consultation to determine whether they were eligible to receive treatment at the clinic. There was no documented criteria that would preclude patients from bio-identical hormone treatment, but the clinical lead advised any patients with a family history of oestrogen driven breast cancer or prostate issues would not be suitable for treatment. Medical history for service users was not comprehensive and was a basic questionnaire, which did not take account of key issues such as co-morbidities, which the service user self-completed. There was no evidence in records that the doctor had reviewed this or discussed it with the service users.
- Further treatment was prescribed without clear records of the decision making process, treatment records, details of medications administered, batch numbers/ date of expiry for injectables or evidence of collection of medication/recall procedures
- The clinical lead told us that patients that were accepted for treatment were initially deemed fit and healthy by him with a low risk of developing complications during treatment. However, the clinical lead's assessment was not documented in patient's medical records and there was not a standard operating procedure outlining admission criteria. The clinical lead told us that patients with a history of oestrogen driven breast cancer and prostate problems were excluded, but assessment criteria was not documented in patients' records.
- There was no documented evidence of the ongoing monitoring of patients' BMI, blood pressure, pulse, allergies/sensitivities, tobacco use, alcohol intake, prescribed or recreational drug use in line with best practice for prescribing oestrogen and testosterone based medication.
- The clinic reported that there had been no cases of unplanned transfer of a patient to another hospital. In the case of staff needing further advice or assistance with a patient, they would contact the clinical lead for guidance.
- In the case of a deteriorating patient, the clinic would dial 999 for ambulance to transfer the patient to a local acute NHS Hospital.

Nursing and support staffing

- There were seven permanent nursing and support staff members employed by the clinic this included: a registered manager, three health and beauty therapists (two of which were trainee dental nurses), one blood analyst/dental technician, and two receptionists.
- The clinic employed a theatre nurse on a sessional basis.
- There were no staffing vacancies at the time of the inspection. Staffing numbers reflected the elective nature of the treatments offered at the clinic.

Medical staffing

- There was one clinical lead employed by the service, with dual registration as a doctor and a dentist, registered with both the GMC and the GDC.
- The clinical lead had full responsibility for all clinical activity undertaken at the clinic.

Emergency awareness and training

- The clinic had an 'Emergency procedures and contingency plans' policy. There was no standalone major incident plan or business continuity plan.The policy outlined actions staff should take immediately in

the event of a loss of water or gas, but did not outline what steps staff should take in the interim to ensure patient safety, for example whether they should suspend treatment and cancel appointments.

- Staff had not received up to date training in medical emergencies. We spoke to a member of staff who did not demonstrate knowledge of what to do in the event of an emergency.
- The clinical lead did not have up to date advanced life support (ALS) training. At the time of the initial inspection, there was no documented evidence that showed whether the theatre nurse had up to date life support training. We escalated this to the senior management team and obtained evidence after the inspection that the theatre nurse was trained in basic life support (BLS).
- In the case of a medical emergency the clinic process would be to dial 999 for an ambulance and transfer to hospital.

Are medical care services effective?

Evidence-based care and treatment (medical care specific only)

- The clinic did not have any standard operating procedures for bio-identical hormones and did not reference applicable guidance for example National Institute for Health and Care Excellence (NICE) guidance NG23 Menopause – Diagnosis and Management and testosterone replacement recommendations. However, the clinic showed us a range of course materials that identified where the formulations for assessing and treating patients with bio-identical hormones originated. The materials used were relevant and were current evidence based guidance from other countries. The course materials set a range of standards and provided examples of practice used in other countries.
- Patients' records did not demonstrate how the clinic complied with the clinical lead's range of course guidance materials and how decisions were made.
- At the time of our inspection audits were not undertaken to monitor compliance with guidance and standards. Senior staff told us that the service did not have an audit programme. This meant that leaders within the service had no demonstrable way to evidence best practice guidance was followed. However, during our inspection we undertook a comprehensive records review and obtained copies of course materials the clinical lead used to determine treatment prescribed. We sought clinical advice on this to assure ourselves regarding patient safety.
- The service did not have policies and standard operating procedures relating to their provision of bio-identical hormones in place at the time of our inspection. However, all staff could tell us what the clinic's generic process was.

Patient outcomes (medical care specific only)

- At the time of our inspection outcomes of people's care and treatment were not routinely collected and monitored. The clinical lead explained that he sees every patient and is aware of their outcomes information, but this is not documented within patients' records nor centrally recorded.
- The clinical lead advised us that intended outcomes were achieved for patients. The patients we spoke with all confirmed that they had had a positive outcome following their treatment. However, the absence of any audits and comprehensive records meant we were not able to assure ourselves that intended outcomes for people were being achieved. The absence of a standard operating procedure also meant expected patient outcomes were not clearly defined.
- The service did not benchmark itself against other similar services. As patient outcomes were not documented the service could not evidence how it had refined techniques or developed over time.
- The service did not participate in relevant local and national audits or peer review exercises. The clinical lead and registered manager were unaware of the Private Health Information Network (PHIN) and the benefits of participating in this. The Private Healthcare Information Network (PHIN)is an independent, not-for-profit organisation that publishes trustworthy, comprehensive data to help patients make informed decisions regarding their treatment options, and to help providers improve standards

Medical care

- The service could not evidence that it used people's outcomes to take improvement action as no patient outcomes information was recorded.
- At the time of our inspection, staff were not involved in any activities to monitor and improve patient outcomes. The service did not hold audit meetings.
- We escalated our concerns regarding the absence of patient outcomes data, standard operating procedures and audits to the service at the time of our inspection. The service provided us with an action plan to address our concerns.

Competent staff

- Staff members did not have appraisals, which was confirmed by staff and the registered manager.
- Three out of nine staff did not have a DBS check undertaken or in place at the time of our inspection. Seven out of nine staff did not have references within their personnel file.
- Three out of nine staff had no evidence they had undertaken an induction in their personnel files.
- Records showed no one had current advanced life support or current first aid training at the time of our inspection. The guidance on the provision of anaesthesia in day surgery (2016) states that staff should be trained to advanced life support standards. We escalated these issues to the provider at the time of our inspection. They provided us with an action plan to address our concerns.
- The registered manager and clinical lead were not able to provide any written evidence of the monitoring of staff competency to undertake key aspects of their roles such as taking bloods and provision of intra-muscular injections. The registered manager and clinical lead told us that they did not maintain or have competency records. This meant the registered manager could not assure himself regarding clinician's effectiveness and the provider could not assure us that staff were competent to perform their roles. We escalated this issue to the provider at the time of the inspection. They provided us with an action plan to address our concerns. Whilst this action plan assured us regarding immediate patient safety concerns, a more comprehensive action plan was sought to address issues going forwards.
- Staff were able to access training opportunities that were relevant to their own and the business' needs. However, discussions regarding staff members' professional development were not documented.
- The service did not have a documented procedure in place for the granting of practicing privileges.
- This service did not have arrangements in place to notify local healthcare providers if a staff member was suspended from duty.

Multidisciplinary working

- The service did not have documented clinical pathways in place at the time of our inspection.
- The clinical lead informed us that he was able to refer patients for appropriate psychiatric support if necessary.

Access to information (medical care only)

- The clinical lead had access to all the information needed to deliver effective care and treatment in a timely way. However, patients' records did not evidence comprehensive risk assessments, care plans, clinical analysis or evidence of decision making at the time of our inspection.
- There was a system in place to ensure that medical records were available to all staff that may be required to provide care and treatment to a patient. However, these records were not comprehensive as discussed above in the records section of this report.
- Copies of care records were not routinely sent to a patient's GP, unless a patient's consent was sought. We saw no evidence that records had been sent to GPs.
- The service had arrangements in place to gain timely results to diagnostic results.
- The service did not have a service level agreement in place with the compound pharmacy that provided their medications.
- There were limited policies available for staff and those that were available were not comprehensive.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards (medical care patients and staff only)

Medical care

- Training records showed that no one at the clinic had had training on the Mental Capacity Act 2005. However, the clinical lead and registered manager could both explain the principles governing the act.
- Staff were aware of the principles for seeking consent. However, we found no evidence in medical records of documented consent for the off-licence medication, which was prescribed.
- Staff told us that they ensured they obtained informed consent from patients for all care and treatment. Staff confirmed individual treatment options, risks and benefits were discussed with each patient who then received a detailed treatment plan and estimate of costs. However, we found no evidence of this in patients' medical records.
- The clinic did not have a policy on consent. The process for seeking consent was not monitored and there was no evidence how the process had been improved to ensure it met with responsibilities, legislation and national guidance.

Are medical care services caring?

Compassionate care

- Patients were treated with dignity, compassion and empathy. We observed staff providing care in a respectful manner. Patients' privacy and dignity was maintained in the theatre and recovery area.
- We spoke with three patients receiving bio-identical hormone treatment. Patients were positive about their experience, described that the clinical lead had taken his time to explain the process to them and given them an appropriate amount of information and time for them to make an informed decision
- We observed all staff maintained privacy and confidentiality for patients on the day of the inspection. Practice computer screens were not overlooked in reception and treatment rooms, which ensured patients' confidential information could not be viewed by others.
- We saw that doors of treatment rooms were closed at all times when patients were being seen.Conversations could not be heard from outside the treatment rooms, which protected patients' privacy.
- We received 21 'tell us about your care' patient comment cards. Patient feedback from comments cards was positive, comments included:

  "All staff are warm and engaging and take the time to get to know you on a personal level".

  "Everyone is so kind the care is fantastic".

  "Levels of customer service are excellent, and the services I have accessed have always been fully explained and tailored to my needs. Follow up and aftercare has also been very professional".

  "Feel listened to by staff here after several disappointing visits to GP/specialist. Have recommended them to a few friends".

Understanding and involvement of patients and those close to them

- Patients reported that they felt listened to and were able to ask questions about their treatment and aftercare.
- Patients underwent initial consultations with the clinical lead carrying out the procedure and individual patient preferences were taken into account as part of this process.
- Patients told us they were kept fully informed and staff were clear at explaining their treatment to them in a way they could understand. Patients told us the clinical lead went through their expectations and explained the treatment clearly.

Emotional support

- Patients reported that the staff had put them at ease and provided emotional support before, during and after the procedure.
- There was no specified counselling service, but patients were given the clinic's phone number and the number of the clinical lead and encouraged to call if they had any questions.

Are medical care services responsive?

We do not currently have a legal duty to rate independent medical services.

Service planning and delivery to meet the needs of local people

Medical care

- The clinic provided bio-identical hormone treatment for private fee paying patients over the age of 18.
- The clinic also provided non regulated cosmetic treatments. We did not inspectthese services.
- The clinic had four treatment rooms. Consultation for bio-identical hormone treatment was carried out in the clinic's treatment rooms.
- Patients could book a consultation at one of the clinic's satellite sites if this was more convenient.

Access and flow

- Patients self-referred to the service. When a patient contacted the service, they were offered an initial consultation with the clinical lead at a time that suited the patient. Patients were given verbal confirmation of fees at the time of booking the initial consultation and again at the consultation itself. Patients were emailed the consultation form to complete and bring with them to the initial consultation.
- Letters were not routinely sent to a patient's GP unless patient permission had been obtained.
- In the previous 12 months, 534 patients had received bio-identical hormone treatment at the service.

Meeting people's individual needs

- The service had a disability discrimination policy. The policy stated the service would make reasonable adjustments, where possible, to ensure disabled persons can access the service.
- The practice had made some reasonable adjustments to try and prevent inequality to patients. The treatment room was accessible to patients with limited mobility and wheelchair users but the toilet was not. The patient information leaflet included a disability access statement, which confirmed this clearly to patients.
- Information leaflets about the services were readily available in all the areas we visited.
- Staff could access a language interpreter if needed. There was space on the consent form for the interpreter to sign and date when patients agreed to treatment.

Learning from complaints and concerns

- The service had a complaints policy in place. The complaints policy stated that complaints would be acknowledged within two working days and investigated and responded to within 20 working days, with the option of a meeting if appropriate.
- Patients we spoke to were unsure whether they had received a leaflet or guidance on the procedure for complaints. However, we did view a 'patient guide' on inspection that detailed the process to follow to complain, although this was not displayed prominently in the clinic. We did not see the 'user complaint form' displayed in the clinic.
- The complaints policy was split in to three stages, 1. Local resolution, 2. Appeals to senior management and 3. Appeals to managing director.
- Where patients were not satisfied with the response to their complaint, they were given information on how to escalate their concerns with the Care Quality Commission (CQC) and the Local Government Ombudsman. The Local Government Ombudsman does not deal with complaints for services of this nature and the correct body to escalate complaints to is the Independent Sector Complaints Adjudication Service (ISCAS).
- The service reported that they had received no complaints in the past 12 months. Staff told us that any patient concerns would be discussed at routine clinic meetings to share learning.

Are medical care services well-led?

Vision and strategy for this this core service

- Whilst the registered manager and clinical lead had a clear vision and strategy, this was not documented. Plans had been made to enable the clinic to increase the number of patients seen for bio-identical hormones and for the introduction of an onsite compound pharmacy.
- Staff were aware of the strategy within the clinic and of their role within it to achieve it.
- There was no written evidence of how the strategy was monitored and reviewed.

Leadership and culture of service

Medical care

- The overall leadership was provided by the registered manager. At the time of our inspection, senior leaders within the clinic did not demonstrate a comprehensive awareness of the information they need to manage the clinic. During our inspection, the clinical lead informed us he was unaware of the latest guidance from Royal College of Surgeons dated April 2016 relating to the requirements of the cosmetic specialist registrar. This meant that processes in the clinic did not consistently reflect best practice guidance.
- Whilst all staff wanted to provide the best service possible, the absence of policies, procedures and clear governance frameworks restricted their capability to do this.
- Staff understood the requirement of the duty of candour. However, the absence of audited reporting mechanisms did not permit the collation of information to enable service improvements.
- The registered manager and clinical lead were visible and approachable.

Governance, risk management and quality measurement (medical care level only)

- The provider did not have effective systems and processes in place to ensure there was appropriate governance and managerial oversight of the clinic. We found no evidence of audits including an absence of records audits, monitoring of patient outcomes audits and no documented evidence of improvement to the quality and safety of the services provided and senior managers confirmed this.
- The service did not have a clear governance framework and management could not evidence that they regularly reviewed the systems that were in place.
- The 15 clinical records we reviewed did not document comprehensive pre-assessments and screening of patients to ensure that risks to the health, safety and welfare to service users were assessed, monitored and mitigated. We asked the clinical lead if other records would contain comprehensive pre-assessments and screening of patients and were advised they would not as it was not the clinical lead's practice to do anything different from what we had witnessed in the 15 clinical records we discussed with him.
- Clinical reasoning for decision-making was not contained within the patients' medical records we reviewed. The clinical lead confirmed otherpatients' records were in line with the 15 records we had reviewed and would not evidence a complete and contemporaneous record being available for each service user that included a record of care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided. The absence of a record keeping audit meant the service leads did not identify this issue and/or address it.
- We observed that there was an absence of risk assessments for staff including a risk assessment for the risk for staff being exposed to hepatitis b if they were not immune. The clinic had not had a legionella assessment despite it being required to do so. Infection control audits were not undertaken at the right frequency. The service did not have a risk register or similar document in place to enable leaders within the clinic to have an oversight of risk.
- There was no documented evidence that staff reported incidents, despite incidents occurring (including the fridge recording temperatures being out of range and the fridge then being broken). Three staff we spoke with were unaware of the term 'incident' and advised that they were unaware of the need to log anything when examples of incidents were given. This was against the provider's own policy. The clinic's leads had not identified the breach.
- The registered manager and clinical lead told us that the clinic did not maintain competency assessment evidence for staff who undertook clinical procedures. This meant there was no documented assurance for managers that staff were clinically competent.
- There was not a comprehensive assurance system and service performance measures in place at the time of our inspection.
- The service did not have arrangements in place to collate information to monitor and manage quality and performance.
- The service did not have a systematic program of clinical internal audit to monitor quality and systems or identify where action should be taken.

- The service did not have robust arrangements for identifying, recording and managing risk issues and mitigating actions.

Public and staff engagement

- The practice had systems in place to seek and act upon feedback from staff members and people using the service. Staff and patients were encouraged to provide feedback on a regular basis either verbally or online. The practice also carried out their own survey with annual analysis. Both survey results were displayed in reception to show patients how their views have been considered.
- Staff told us their views were sought and listened to and that they were confident to raise concerns or make suggestions to the registered manager.
- The service had a system in place to ensure people using the service were provided with details of the fees, payment method and the terms and conditions of service.
- The senior leadership team and staff told us that they work collaboratively to discuss how the service could be improved. Senior leaders told us they listened to concerns and staff confirmed this.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

Incidents

- There were no 'never events' reported in relation to the surgical services at the clinic. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- There were no incidents reported in relation to surgery.
- The service had an 'Adverse events and near miss policy' which details the actions staff should take to report an incident and the escalation process to follow. The policy also outlines examples of what would constitute a clinical 'near miss'; however staff were not aware of the content of this policy. Staff were unaware of any documentation to report incidents.
- Staff told us they would inform the practice manager of any 'incidents'; however they were unaware whether an accident book was available to record accidents or if there was a process to investigate incidents.We were not assured staff knew how to identify and report an incident.
- Staff we spoke to were unsure about what would constitute an incident for reporting purposes.
- A patient we spoke to reported they had an adverse reaction to penicillin post-surgery. The clinic prescribed alternative medication, but this was not documented as an incident in line with the 'Adverse events and near miss policy'.
- The clinic reported there had been no patient deaths relating to surgery.
- Staff were aware of their responsibilities under the Duty of Candour. Duty of candour is a requirement under The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 on a registered person who must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.
- Staff did not complete incident report forms when incidents occurred, for example, when the fridge temperatures went out of range and the fridge subsequently broke. This is against the clinic's health and safety policy. Therefore, the clinic management did not assess the risks to the health and safety of service users receiving care or treatment; and did not do all that was reasonably practicable to mitigate any such risks.

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

- The service did not use a clinical quality dashboard.
- The service did not have any documented evidence of how it monitored safety and used the results for learning. However, the registered manager and clinical lead advised us that the clinical lead had overall clinical responsibility and that the general day to day running of the clinic was the registered manager's responsibility.

Cleanliness, infection control and hygiene

- The clinic rooms and theatre area were visibly clean and tidy. The service had a cleaning schedule in place that covered all areas of the premises and detailed what and where equipment should be used. We could not see evidence of national guidance on colour coding equipment to prevent the risk of infection spreading but staff told us that the cleaner brought their own cleaning products and supplies.

- Staff were not sure whether there was a spillage kit available to clear up any spillage of blood or body fluids.At the time of our inspection we did not see evidence of the clinic stocking a spillage kit. Staff told us they would use bleach to clean up blood or body fluids.
- There was a generic written infection control policy, which included minimising the risk of blood-borne virus transmission which included Hepatitis B. Senior managers undertook annual reviews of infection control and prevention standards.The government Health Technical Memorandum (HTM 01-05) stipulates that these reviews should be carried out minimally on a six monthly basis. Senior managers were unaware of this code.
- Senior managers had not arranged for legionella assessments for water sources within their premises to be undertaken. This meant that reliable systems were not in place to protect people from a healthcare acquired infection.
- There were no cases of Methicillin-resistant Staphylococcus aureus (MRSA) bacteraemia, Methicillin-sensitive Staphylococcus aureus (MSSA) bacteraemia, Clostridium difficile (C.diff) or Escherichia coli (E. coli) reported by the clinic. The clinic did not screen for these bacteraemia as part of the pre-surgery assessment.
- There were no surgical site infections reported by the clinic.
- The clinic did not have a system in place to improve and review safety systems and processes.

Environment and equipment

- The theatre and treatment rooms were tidy and free of clutter.
- Resuscitation equipment and some emergency medicines were present at the time of the initial inspection; however the contents of the resuscitation trolley did not meet those recommended by the Resuscitation Council. The ambubag, glyceryl trinitrate spray, Salbutamol, dispersible aspirin, glucagon, buccal midazolam and spacer device were all missing. We escalated this issue to the provider as an immediate patient safety risk and when we returned the missing items had been ordered and the clinic was awaiting delivery of one outstanding medicine.
- There was an automated external defibrillator (AED).
- We saw records that showed the emergency medicines and equipment were checked on a daily check. Staff knew the location of the emergency equipment.
- At the time of our inspection the clinic could not evidence that any staff member had basic first aid training, basic life support training or advanced life support training. The registered manager told us that all staff, excluding the clinical lead, had not been trained in the use of the resuscitation trolley.
- The staff told us they ordered single use gowns and scrubs for each surgical procedure.
- There were a large number of expired consumables stored in trolleys and cupboards in the clinic, these included adhesive dressings with expiry dates ranging from 24 December 2008 to 12 June 2010, one box of mesobelle needles, one bag of transport swabs expiry date January 2011, six rolls of micropore tape, one box of spinal needles and 20 ampules of steripod water for injection. There were also packs of syringes, hand wipes and two trays of vacutainers for blood collection expiry October 2016 and December 2016.
- There were personal items stored alongside clinical consumables in a drawer and cupboard in clinic room four and the clinic storeroom.

Medicines

- There was a 'management of medicines policy' at the clinic. However, we found multiple breaches of the policy during our inspection, these included: the service not ensuring the safe storage and security of medicines, not recording delivery and collection of medicines and not reporting incidents involving medication, adverse drug reaction and the monitoring of emergency medication.Medications were not kept in locked cupboards or in clinic rooms, leaving it unsecure and allowing for unauthorised access. The clinic's policy states: 'Medicines are stored in a locked cupboard or controlled area' and our findings on inspection did not reflect this.
- Staff members stored their own medications alongside those prescribed to patients. Topical medications were stored on a racking shelf in the store room, which was not temperature controlled, therefore there was no way of verifying whether the medications were being stored

in line with their storage instructions. The 'management of medicines policy' states medicines requiring refrigeration would be stored in a lockable fridge, the fridge was faulty and had been recording out of range temperatures. This had not been reported as incident.

- For prescribed medications, there was no record in the prescription book that the patient had collected their medication. The last date for collection of medication in the book was the 18 August 2015. However, the clinic had recorded that medication was ordered up until 9 March 2017. All collection dates between 18 August 2015 and9 March 2017were incomplete.
- Prescribed medication was not consistently recorded as delivered in the prescription book. This was a breach of the clinic's 'management of medicines policy' under the ordering and receipt of medicines section.
- There was no procedure for controlled drugs. Controlled drugs were not stored appropriately and there was no controlled drug log book.
- There was no oversight for private prescriptions or audit of medication prescribed by the clinical lead.
- We found expired prescription medication for patients in a cupboard in a clinic room. This included Ceftriaxone solution injections (expiry January 2017) an unidentified medicine. The medication had not been disposed of in line with the 'Management of medicines policy'. We raised this with the clinical lead and registered manager, who confirmed the unidentified medication had been brought in by a patient, for identification by the clinical lead, and should have been disposed of in line with the policy. When we returned on our unannounced inspection, the expired medication had been disposed of.
- We found expired medication in use at the clinic, this included: four vials of Somatropin (a human growth hormone), one box of Ceftriaxone, 17 vials of Hydroxocobalamin (Vitamin B12a) and 12 bottles of bacteriostatic saline. This was a risk to patient safety, we escalated this to the clinical lead and registered manager and they took action to remove the expired medications. The clinic did not have records of which patients may have been prescribed expired medications as the prescriptions were not routinely audited and batch numbers and expiry dates weren't recorded in the patients' records. Patients who were undergoing liposuction procedures told us that they were prescribed antibiotic medication. However, of the three files we reviewd on the initial inspection, one patient record contained no copies of any prescriptions.This meant the clinic was unable to identify which patients had received a specific medication.
- We found expired medication in surgical use at the clinic; this included two vials of 2ml 5% Lidocaine with expiry dates of August 2016 which were kept in a box that was dated May 2018. We found an open vial of Lidocaine with expiry date August 2016; three vials in total were open and stored in the cupboard.
- There were no documented audits of stocks of medication held. The clinic did not hold an inventory of the medicines held and there was no robust process to identify and dispose of expired medications. There was no clear guidance in the policy as to who was responsible for checking all medications for expiry dates. The policy references emergency medicines only.
- A patient we spoke to had an intolerance to penicillin but had not disclosed this, as it was not an allergy. The patient was prescribed penicillin and was sick. The clinic prescribed alternative antibiotics but the screening paperwork and consultation had not picked this up. This was also a breach of the clinic's 'management of medicines policy' as the policy advises in the adverse drug reaction section the that 'Prior to any medication being prescribed, the patient is informed about possible commonly recognised adverse reactions or side effects' and '…the event must be recorded as a significant event, so that this information may be used for auditing purposes. MHRA should also be informed of any serious adverse reactions.' There was no evidence either of these points had been followed.

Records

- Staff used paper based patient records and these were stored in lockable filing cabinets in the clinic.
- Records for patients who were booked in to clinic were kept behind the reception desk. There was no locked drawer or secure storage in the reception area for patient files. Although the main door to the clinic is locked, reception was not continually manned, so records were unattended at times which had the potential to allow for unauthorised access.

- We looked at the records of nine patients. We found there was a gap in the recording of consultations and medical history in patient records.

  There was no documented evidence of a mandatory 14 day cooling off period for cosmetic surgery procedures, in line with the GMC Guidelines for Cosmetic Surgery. We reviewed one patient record which showed the patient had paid the deposit on the 29 November 2016 and the procedure had taken place on the 5 December 2016. There was no evidence of when the consultation and pre-assessment had taken place on the treatment record.

- There was no documented evidence that fees had been discussed at the consultation but patients we spoke to confirmed they were aware of the fees and discussed these at the consultation.

- Patients' medical history in relation to surgery was not comprehensive and was filled in by the patient. There was space on the 'new patient pro-forma' for additional medical history notes, but there was no evidence that further history had been discussed with the clinical lead as these were not completed in the records we reviewed. Consultations and follow up appointments were poorly documented and there were no further medical notes in the records.

- Patients filled in a 'precautions' list on the back of the 'new patient pro-forma'. The tick-list was the only pre-surgery risk assessment evidenced in the patient records. The tick-list covered pregnancy, allergies, anaphylaxis, diseases, blood pressure problems, medication (specifically anticoagulants), bleeding and bruising issues, skin problems, sensitivity to local anaesthetic and other treatments.

- There was no pre-operative risk assessments, such as for thromboembolism (VTE), documented anywhere inpatients' records.

- There was no documented evidence of basic patient information such as blood pressure, BMI or weight in the surgical consultation records.

- Of the three patient records reviewed on the day of the initial inspection, one record had a mistake recorded on the 'checklist of items used' in relation to one of the medications used during surgery. We escalated this to the clinical lead and he confirmed it was an administrative error.

- Patient records did not evidence assessment of a patient's emotional or psychological state prior to surgery.

- The documents used to screen patients prior to surgery were not robust enough to pick up potential patient risks.

Safeguarding

- The service had a safeguarding policy which outlined how to report safeguarding issues.

- The service had information on how to report safeguarding issues held in a policies folder at the clinic.

- No staff within the service had current safeguarding training. Staff in the service had received safeguarding training in 2013 (although the level could not be verified) but the training had expired in 2016 and had not been refreshed. The registered manager was not aware that this training needed to be refreshed every three years.

- The clinical lead did not have current adult or childrens safeguarding training and advised he was unaware of the need to update this training.

- There were no safeguarding incidents reported by the clinic in the past 12 months.

Mandatory training

- The service had not provided current fire safety, manual handling and infection control training to its staff members. At the time of our inspection on 1 March 2017, there was no evidence staff had received this training in staff files and there was no training matrix or a subject list in place to stipulate what training was required for each staff member.

- We requested a list from the registered manager of what subjects were considered mandatory training and this list was not comprehensive and excluded key areas including moving and handling, infection control and the use of display screen equipment. The list supplied

as mandatory training subjects comprised of: basic health and safety including COSHH, fire safety, safeguarding and laser safety core of knowledge for laser therapists.

- The certificates for staff training in health and safety were undated and were not accredited to an issuing authority or body. The registered manager confirmed to an inspector that these certificates were over 12 months old and that there was not a set frequency for training to be repeated and/or updated. Therefore the service did not ensure that persons providing care or treatment to service users had the qualifications, competence, skills and experience to do so safely.
- The provider did not have a comprehensive health and safety policy in place at the time of our inspection and the policy was not followed. The policy states that staff will receive an annual update on moving and handling training. The registered manager told us that staff did not have moving and handling training, as it is not applicable to their role. Staff files confirmed that staff did not receive training in this area. The Manual Handling Operations Regulations 1992 do not exclude the clinic's staff from the application of these regulations and therefore staff should receive training in this area.
- Staff files did not evidence COSHH training, fire safety awareness training, basic risk assessment training nor any evidence of regular updates in essential areas including safeguarding training.

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

- Patients had an initial consultation to determine whether they were eligible to receive treatment at the clinic. There was no documented admission criteria that would preclude patients from surgery. There was a 'precautions' tick list on the back of the 'new patient proforma' but this was the only evidence of a pre-surgery risk assessment. The clinical lead used his clinical knowledge to determine whether a patient was suitable for surgery, but did not document his clinical judgments.
- The clinic showed us the protocol for the use of the equipment which included indications, contraindications and cautions. The pre-assessment screening records did not reflect contraindications including a BMI calculation, whether a patient smoked, if a patient has poorly controlled diabetes, patients' unwillingness to consider multiple procedures, whether patients were ambulant and assessment of a patient's mental state.
- The clinic had blood pressure equipment to monitor a patient's blood pressure and pulse during a procedure. There was no evidence in the patients' records that this had been monitored and documented throughout the procedure, nor that blood pressure checks had taken place prior to surgery.This was a risk to patient safety, as no regular monitoring of the patient throughout the procedure, was documented as having taken place.
- Patients undergoing surgical procedures were treated under local anaesthetic or sedation (Midazolam); no general anaesthetic was used for procedures carried out by the clinic.
- The clinical lead told us the patients that were accepted for treatment were generally fit and healthy with a low risk of developing complications during or after surgical treatment. However, there was no documented admission criteria, detailed patient assessment within clinical records or record of the clinical's lead decision making rationale to confirm this decision.
- The clinic reported that there had been no cases of unplanned transfer of a patient to another hospital and no complications during surgery.
- In the case of a deteriorating patient, the clinic would dial 999 for an ambulance to transfer the patient to a local acute NHS Hospital.
- The clinic treated one patient per day in surgery, enabling the clinical lead and the theatre nurse to provide one on one care to the patient.
- The clinical lead did not undertake or use the World Health Organisation five steps to safer surgery including the surgical safety checklist or any other checklist that ensured comprehensive checks prior to, during and following surgery. Therefore, the clinic were not assessing the risks to the health and safety of service users receiving care or treatment.

Nursing and support staffing

- There was one theatre nurse working on a practicing privileges basis.

- There were seven permanent nursing and support staff members employed by the clinic this included: a registered manager, three health and beauty therapists (two of which were trainee dental nurses), one blood analyst/dental technician, and two receptionists.
- There were no staffing vacancies at the time of the inspection. Staffing numbers reflected the elective nature of the treatments offered at the clinic.
- All patients were admitted for planned day case surgery and staffing was determined prior to patients attending for surgery.

Medical staffing

- There was one clinical lead employed by the service with dual registration as a doctor and a dentist, registered with both the GMC and the GDC.
- The clinical lead had full responsibility for all clinical activity undertaken at the clinic.
- Surgical procedures and pre-operative assessments were carried out by the clinical lead on a day case basis under local anaesthetic.
- The theatre team for a liposuction procedure consisted of a clinical lead, and a theatre/recovery nurse.

Emergency awareness and training

- The clinic had an 'Emergency procedures and contingency plans' policy. There was no standalone major incident plan or business continuity plan.The policy outlined actions staff should take immediately in the event of a loss of water or gas, but did not outline what steps staff should take in the interim to ensure patient safety, for example whether they should suspend treatment and cancel appointments.
- Staff had not received up to date training in medical emergencies. We spoke to a member of staff who did not demonstrate knowledge of what to do in the event of an emergency.
- The clinical lead did not have up to date advanced life support (ALS) training. There was no documented evidence on the day of the initial inspection that showed whether the theatre nurse had up to date life support training. We escalated this to the senior management team and obtained evidence after the inspection that the theatre nurse was trained in basic life support (BLS).
- In the case of a medical emergency the clinic process would be to dial 999 for an ambulance and transfer to hospital.

Are surgery services effective?

Evidence-based care and treatment

- The clinic showed us the protocol for the use of the liposuction procedure that had been provided by the equipment manufacturer. The protocol was thorough, comprehensive and covered some best practice. However, the clinic did not consistently follow this protocol for example the clinic's pre-assessment screening records did not reflect contraindications including a BMI calculation, whether a patient smoked, if a patient has poorly controlled diabetes, patients unwillingness to consider multiple procedures, whether patients were ambulant and assessment of a patient's mental state.
- The clinic did not have its own standard operating procedure or pathway which governed factors specific to the clinic or updates in best practice since the protocol was issued in 2014.
- At the time of our inspection audits were not undertaken to monitor compliance with guidance and standards. Senior staff told us that the service did not have an audit programme. This meant that leaders within the service had no demonstrable way to evidence best practice guidance was followed.
- All staff could tell us what the clinic's generic process was for admission of a liposuction patient.
- The service had specialised equipment that was appropriately maintained in line with the manufacturer's guidance.
- The clinical lead did not undertake or use the World Health Organisation surgical safety checklist or any other checklist to ensure appropriate checks prior to, during and following surgery.

Surgery

- The clinical lead was unaware of the latest guidance from Royal College of Surgeons dated April 2016 relating to the requirements of the cosmetic specialist register. This meant the clinic did not have plans in place to address the need for a member of staff to be registered on the cosmetic specialist register.
- The clinical lead told us he was unaware of the Professional Standards for Cosmetic Surgery provided by the Royal College of Surgeons (RCS). This meant there was a risk that patients were not receiving treatment in line with best practice guidance.
- The service pre-assessment did not include appropriate and relevant psychiatric history. We escalated this issue at the time of the inspection. The provider has given us an action plan to address this issue.
- The service did not use the RCS audit tool that covers pre-assessment and consultation as they were not aware of it. We escalated this issue at the time of our inspection. The provider has given us an action plan to address this issue.

Pain relief

- The service did not have a pain management policy. However, patients told us their pain was effectively managed post-operatively.

Patient outcomes

- At the time of our inspection surgical outcomes of people's care and treatment were not routinely collected and monitored. The clinical lead explained that he sees every patient and is aware of their outcomes information, but this is not documented within patients' records nor centrally recorded.
- The service did not routinely collate Q-PROM data in accordance with best practice.
- The clinical lead advised us that intended surgical outcomes were achieved for patients. The patients we spoke with all confirmed that they had had a positive outcome following their treatment. However, the absence of any audits and comprehensive records meant we were not able to assure ourselves that intended outcomes for people were being achieved.
- The service did not benchmark itself against other similar services. As patients' surgical outcomes were not documented the service could not evidence how it had refined techniques or developed over time.
- The service did not participate in relevant local and national audits or peer review exercises. The clinical lead and registered manager were unaware of the Private Health Information Network (PHIN) and the benefits of participating in this. The Private Healthcare Information Network (PHIN)is an independent, not-for-profit organisation that publishes trustworthy, comprehensive data to help patients make informed decisions regarding their treatment options, and to help providers improve standards.
- The service could not evidence that it used people's outcomes to take improvement action as no patient outcomes information was recorded.
- At the time of our inspection, staff were not involved in any activities to monitor and improve patient outcomes. The service did not hold audit meetings.
- We escalated our concerns regarding the absence of patient outcomes data, standard operating procedures and audits to the service at the time of our inspection. The service provided us with an action plan to address our concerns.

Competent staff

- Staff members did not have appraisals, which was confirmed by staff and the registered manager.
- Three out of nine staff did not have a DBS check undertaken or in place at the time of our inspection. Seven out of nine staff did not have references within their personnel file.
- Three out of nine staff had no evidence they had undertaken an induction in their personnel files.
- Records showed no one had current advanced life support or current first aid training at the time of our inspection. The guidance on the provision of anaesthesia in day surgery (2016) states that staff should be trained to advanced life support standards. We escalated these issues to the provider at the time of our inspection. They provided us with an action plan to address our concerns.

- The registered manager and clinical lead were not able to provide any written evidence of the monitoring of staff competency to undertake key aspects of their roles such as taking bloods and provision of intra-muscular injections. The registered manager and clinical lead told us that they did not maintain or have competency records. This meant the registered manager could not assure himself regarding clinician's effectiveness and the provider could not assure us that staff were competent to perform their roles. We escalated this issue to the provider at the time of the inspection. Whilst this action plan assured us regarding immediate patient safety concerns, a more comprehensive action plan was sought to address issues going forwards.
- Staff were able to access training opportunities that were relevant to their own and the business' needs. However, discussions regarding staff members' professional development were not documented.
- The service did not have a documented procedure in place for the granting of practicing privileges.
- This service did not have arrangements in place to notify local healthcare providers if a staff member was suspended from duty.
- The clinical lead undertook relevant continuing professional development activities and provided evidence of this. The registered manager assured himself that the clinical lead underwent revalidation and had annual appraisals by another professional.

Multidisciplinary working

- All team members were aware who had overall responsibility for each patient's care.
- The clinical lead informed us that he was able to refer patients for appropriate psychiatric support if necessary.
- The service did not have an escalation policy. All staff told us they would contact the clinical lead and dial 999 in the event of an emergency.

Access to information

- The clinical lead had access to all the information needed to deliver effective care and treatment in a timely way. However, patients' records did not evidence comprehensive risk assessments, care plans, clinical analysis or evidence of decision making at the time of our inspection.
- There was a system in place to ensure that medical records were available to all staff who may be required to provide care and treatment to a patient. However, these records were not comprehensive as discussed above in the records section of this report.
- Copies of care records were not routinely sent to a patient's GP, unless a patient's consent was sought. We saw no evidence that records had been sent to GPs.
- The service did not have a service level agreement in place with the pharmacy who provided their medications.
- There were limited policies available for staff and those that were available were not comprehensive.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Training records showed that no one at the clinic had had training on the Mental Capacity Act 2005. However, the clinical lead and registered manager could both explain the principles governing the act.
- Staff were aware of the principles for seeking consent. However, we found no evidence in medical records of documented consent of a two stage consent process.
- Staff were aware of the principles for seeking consent. However, we found no evidence in medical records of documented consent. Staff confirmed individual treatment options, risks and benefits were discussed with each patient who then received a detailed treatment plan and estimate of costs, but we found no evidence of this in patients' medical records.
- The clinic did not have a policy on consent. The process for seeking consent was not monitored and there was no evidence how the process had been improved to ensure it met with responsibilities, legislation and national guidance.

Are surgery services caring?

Compassionate care

Surgery

- Patients were treated with dignity, compassion and empathy. We observed staff providing care in a respectful manner. Patient's privacy and dignity was maintained in the theatre and recovery area.
- We spoke with six patients. All the patients said they thought staff were kind and caring and gave us positive feedback about ways in which staff showed them respect and ensured that their dignity was maintained. The comments received included: "absolutely lovely nurse" who was present during the procedure. Another patient reported the clinical lead "has a brilliant way about him".
- We observed all staff maintained privacy and confidentiality for patients on the day of the inspection. Practice computer screens were not overlooked in reception and treatment rooms which ensured patients' confidential information could not be viewed by others.
- We saw that doors of treatment rooms were closed at all times when patients were being seen.Conversations could not be heard from outside the treatment rooms which protected patient privacy.
- Patients were seen individually for liposuction procedures and there were no other patients booked in to the surgery suite at the same time.
- We received 21 'tell us about your care' patient comment cards. Patient feedback from comments cards was positive, comments included:

  "All staff are warm and engaging and take the time to get to know you on a personal level".

  "Everyone is so kind the care is fantastic".

  "All treatments carried out with care and respect".

  "Staff very caring, treated with dignity and respect. The environment appears very safe and healthy. Everything was explained and I have always understood what the procedures were".

Understanding and involvement of patients and those close to them

- Patients reported that they felt listened to and were able to ask questions about their treatment and aftercare.
- Patients underwent initial consultations with the clinical lead carrying out the procedure and individual patient preferences were taken into account as part of this process.
- Patients told us they were kept fully informed and staff were clear at explaining their treatment to them in a way they could understand. Patients told us the clinical lead went through their expectations and explained the procedure clearly in the initial consultation and on the day of the procedure.

Emotional support

- Patients reported that the staff had put them at ease and provided emotional support before, during and after the procedure.
- One patient reported they had felt slightly anxious on the day of the procedure and the clinical lead had talked through the process which had put them at ease.
- There was no specified counselling service, but patients were given the clinic's phone number and the number of the clinical lead and encouraged to call if they had any questions or needed support post operatively.

Are surgery services responsive?

Service planning and delivery to meet the needs of local people

- The clinic was open four days per week beginning at 9:00am with varied closing times to match patients' appointment time needs.
- The clinic provided liposuction surgery for private fee paying patients over the age of 18. The surgery was undertaken on a day case basis and no overnight accommodation was provided.
- The clinic had one theatre referred to as a 'surgery suite' where all of the liposuction procedures took place.
- Theatre support staff were booked for surgery once the patient had booked their appointment with the clinic.
- There was an initial assessment/consultation process but there was no written admission criteria that would identify patients that were unsuitable for the procedure. The clinical lead used his clinical judgement to determine if patients were suitable for the bodyjet

liposuction procedure. The clinic did not consistently follow the protocol provided by the liposuction equipment manufacturer, for example the clinic's pre-assessment screening records did not reflect contraindications including a BMI calculation, whether a patient smoked, if a patient has poorly controlled diabetes, patient's unwillingness to consider multiple procedures, whether patients were ambulant and assessment of a patient's mental state.

- Patients could seek an appointment at one of the clinics satellite locations for consultations if this was more convenient, but surgery was always performed at the main site.

Access and flow

- Patients self-referred to the service. When a patient contacted the service they were offered an initial consultation with the surgeon at a time that suited the patient. Patients were given verbal confirmation of fees at the time of booking the consultation and again at the consultation itself.
- The clinic was a small service with no waiting times. There were no issues around staff capacity and procedures were pre-planned once the patient confirmed they wanted to go ahead.
- Appointments were made on the computer and patients were booked in to the diary with their name and the person that they were seeing.
- Discharge letters were not routinely sent to a patient's GP unless patient permission had been obtained.
- Patient records showed patients were offered a follow up appointment after their procedure, where they were assessed by the clinical lead. Records we viewed showed the timings ranged from three days post operatively to three weeks post operatively, to suit the needs of the patient.
- In the previous 12 months, records showed that there had been nine bodyjet procedures performed. Eight patients had undergone the bodyjet liposuction procedure and one patient had been treated twice.

Meeting people's individual needs

- The service had a disability discrimination policy. The policy states the service would make reasonable adjustments, where possible, to ensure disabled persons can access the service.
- The practice had made some reasonable adjustments to try and prevent inequity to patients. The treatment room was accessible to patients with limited mobility and wheelchair users but the toilet was not. The patient information leaflet included a disability access statement which confirmed this clearly to patients. Staff would work with patients to seek a dental practice with full access as appropriate.
- Information leaflets about the services were readily available in all the areas we visited.
- Staff could access a language interpreter if needed. There was space on the consent form for the interpreter to sign and date when patients agreed to treatment.
- Patients reported they were told they needed to have transport to take them home after the procedure as they would be unable to drive themselves home post operatively. Staff checked patients had someone to collect them on the day of the procedure.
- The practice had an equality and diversity statement in place to support staff in understanding and meeting the needs of patients.

Learning from complaints and concerns

- The service had a complaints policy in place. The complaints policy stated that complaints would be acknowledged within two working days and investigated and responded to within 20 working days, with the option of a meeting if appropriate.
- Patients we spoke to were unsure whether they had received a leaflet or guidance on the procedure for complaints. However, we did view a 'patient guide' on inspection that detailed the process to follow to complain, although this was not displayed prominently in the clinic. We did not see the 'user complaint form' displayed in the clinic.
- The complaints policy was split in to three stages, 1. Local resolution, 2. Appeals to senior management and 3. Appeals to managing director.
- Where patients were not satisfied with the response to their complaint, they were given information on how to

escalate their concerns with the Care Quality Commission (CQC) and the Local Government Ombudsman. The Local Government Ombudsman does not deal with complaints for services of this nature and the correct body to escalate complaints to is the Independent Sector Complaints Adjudication Service (ISCAS).

- The service reported that they had received no complaints in the past 12 months. Staff told us that any patient concerns would be discussed at routine clinic meetings to share learning.

Are surgery services well-led?

Vision and strategy for this this core service

- The service had a clear vision and strategy in place, but this was not documented. Plans were in place for this service to be continued at the moment.
- Staff were aware of the strategy within the clinic and of their role within it to achieve it.
- There was no written evidence of how the strategy was monitored and reviewed.

Leadership / culture of service related to this core service

- At the time of our inspection senior leaders within the clinic did not demonstrate a comprehensive awareness of the information they need to manage the clinic. The clinical lead was unaware of the best practice guidance regarding volumes of liposuction removal and whether this should be under general anaesthetic or local anaesthetic. The clinical lead and registered manager were unaware of the private health information network (PHIN), the World Health Organisation (WHO) surgical checklist and the GMC guide for record keeping and its contents
- The service leadership and culture are the same throughout the clinic. We have reported about the governance processes under this section of the medicine service within this report.

Governance, risk management and quality measurement

- The service governance processes are the same throughout the clinic. We have reported about the governance processes under this section of the medicine service within this report.

Public and staff engagement

- The clinic public and staff engagement processes have been reported on under the medicine service within this report.

Community dental services

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

We carried out an announced comprehensive inspection on 1 March 2017 to ask the practice the following key questions; Are services safe, effective, caring, responsive and well-led?

Background

Re-Enhance Dental Practice is a dental practice providing private treatment for adults and children The practice is based on the ground floor of a two storey mid property. There is one dental treatment room and a dedicated decontamination room for sterilising dental instruments. Limited disabled parking is available outside the premises and additional car parking is available on the side-streets near the practice. Access for wheelchair users or pushchairs is possible via the step-free ground floor entrance. The practice employs two dentists, one dental hygienist and two trainee dental nurses.

The service is open from Tuesday - Friday, dental services are predominantly only available on Wednesdays but appointments can be arranged on other days of the week by prior arrangement.

The principal dentist is the nominated individual. A nominated individual is a person who is registered with the Care Quality Commission (CQC) to have overall responsibility for the service.

Our key findings were:

- The practice was visibly clean.
- The practice had systems for recording incidents and accidents but staff were unfamiliar with this.
- Practice meetings were held on a regular basis but the minutes of meetings did not evidence staff discussion and learning.
- The practice had a safeguarding policy and staff were aware on how to escalate safeguarding issues for children and adults should the need arise.
- Staff had not received annual medical emergency training. Equipment for dealing with medical emergencies reflected guidance from the resuscitation council.
- Dental professionals provided treatment in accordance with current professional guidelines.
- Patient feedback was positive.
- Patients could access urgent care when required.

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the practice was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008

The inspection took place on 1 March 2017 was led by a CQC inspector and supported by a dental specialist advisor.

Prior to the inspection, we asked the practice to send us some information that we reviewed. This included the complaints they had received in the last 12 months, their latest statement of purpose, and the details of their staff members including proof of registration with their professional bodies.

During the inspection, we spoke with the practice manager, both dentists and both trainee dental nurses. We also reviewed policies, procedures and other documents.

We informed the NHS England area team that we were inspecting the practice; however we did not receive any information of concern from them.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

Community dental services

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection.

Are community dental services safe?

Reporting, learning and improvement from incidents

- The system to learn from and make improvements following any accidents, incidents or significant events required improvement. Staff told us they would inform the practice manager of any incidents, they were unaware whether an accident book was available to record accidents or if there was a process to investigate incidents.
- Staff were aware of their responsibilities under the Duty of Candour. [Duty of candour is a requirement under The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 on a registered person who must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity].
- Patients were told when they were affected by something that went wrong, given an apology and informed of any actions taken as a result.

Reliable safety systems and processes (including safeguarding)

- The practice had policies and procedures in place for child protection and safeguarding adults. This included contact details for the local authority's safeguarding team, social services and other agencies including the Care Quality Commission. Staff had not received training to the recommended level two; There was a documented reporting process available for staff to use if anyone made a disclosure to them. This did not include and identify the practice's safeguarding lead.
- A risk management process had not been undertaken for the safe use of sharps (needles and sharp instruments).Staff confirmed that only the dentists were permitted to re-sheath needles where necessary in order to minimise the risk of inoculation injuries to staff and disposable matrix devices were in use.
- The practice manager told us that they were registered to receive safety alerts from the Medicines and Healthcare products Regulatory Agency (MHRA). (The MHRA is the UK's regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness). However, evidence of the last safety alert that had been acted upon could not be found.

Medical emergencies

- Staff had not received up to date training in medical emergencies. We spoke to a member of staff who did not demonstrate knowledge of what to do in the event of an emergency. Equipment and emergency medicines were present but these were not in line with the Resuscitation Council UK guidelines (variation identified above in the medicine report in the same section). There was an automated external defibrillator (AED) [An AED is a portable electronic device that analyses life threatening irregularities of the heart and delivers an electrical shock to attempt to restore a normal heart rhythm]. We saw records that showed the emergency medicines and equipment were checked regularly and all stock was within the expiry date. Staff knew the location of the emergency equipment.

Staff recruitment

- The practice recruitment policy was not in line with the requirements of schedule 3 of the Health and Social care Act . We reviewed personnel files, including for a recently recruited member of staff, and found appropriate recruitment checks had not been undertaken prior to employment. For example, proof of identification, references, qualifications, registration with the appropriate professional body and the appropriate checks through the Disclosure and Barring Service. Records of Hepatitis B immunisation were not available and risk assessments had not been carried out on staff that were involved with exposure prone procedures but could not demonstrate immunity.

Monitoring health & safety and responding to risks

- A health and safety policy was available and annual health and safety risk assessments were carried out by the registered manager.
- There were arrangements in place to meet the Control of Substances Hazardous to Health 2002 (COSHH) regulations in relation to domestic cleaning products. We looked at the COSHH file and found that risks (to patients, staff and visitors) associated with substances hazardous to health had not been identified for all hazardous substances.

Infection control

- The systems to reduce the risk and spread of infection could be improved. There was a generic written infection control policy which included minimising the risk of blood-borne virus transmission which included Hepatitis B. The practice had broadly followed the guidance on decontamination and infection control issued by the Department of Health, namely 'Health Technical Memorandum 01-05 -Decontamination in primary care dental practices (HTM 01-05)'. This document and the practice policy and procedures on infection prevention and control were accessible to staff.
- We looked at the facilities for cleaning and decontaminating dental instruments. The practice had a designated decontamination room in accordance with HTM 01-05 guidance. A trainee dental nurse showed us how instruments were decontaminated. They wore disposable gloves rather than heavy duty gloves and did not wear protective eyewear or a disposable apron while instruments were decontaminated. Instruments were scrubbed manually under cold water before immersing in an ultrasonic bath. We asked if any checks were carried out to ensure the efficacy of the ultrasonic bath and staff confirmed that tests were not undertaken and were unfamiliar with the recommended testing. Instruments were visually inspected prior to being placed in an autoclave (sterilising machine). An illuminated magnifier was not available for this process, an illuminated magnifying device is recommended to enable staff to inspect instruments effectively.
- We saw instruments were placed in pouches after sterilisation but these were not dated to indicate when they should be reprocessed if left unused. Staff were unfamiliar with the recommended timeframe for the storage of sterilised instruments.
- There was evidence of daily and weekly tests being performed to check the steriliser was working efficiently and a log was kept of the results. We saw evidence the parameters (temperature and pressure) were regularly checked to ensure equipment was working efficiently in between service checks.
- We observed how waste items were disposed of and stored. The practice had a contract with a clinical waste contractor. We saw the different types of waste were appropriately segregated and stored at the practice. This included clinical waste and safe disposal of sharps. We noted that the sharps container was located on the floor of the dental treatment room; this was immediately moved onto the work surface by a dentist.
- Staff broadly confirmed to us their knowledge and understanding of single use items and how they should be used and disposed of which was in line with guidance, with the exception of single use stainless steel burs. We noted that a number of these had been sterilised and placed back into the bur rack for re-use. These were immediately discarded in the sharps container.
- We looked at the treatment rooms where patients received dental examinations and treatment. The rooms and equipment were visibly clean. Separate hand wash sinks were available with good supplies of liquid soap and alcohol gel. Patients were given a protective bib and safety glasses to wear each time they attended for treatment. There were good supplies of protective equipment for patients and staff members during treatment.
- A risk assessment process for Legionella had not been carried out. The practice provided evidence of annual testing of the water which confirmed that levels of bacteria were within safe parameters. This process ensured the risks of Legionella bacteria developing in water systems within the premises had been identified and preventive measures taken to minimise risk of patients and staff developing Legionnaires' disease. (Legionella is a bacterium found in the environment which can contaminate water systems in buildings). Staff told us they would arrange to have a new legionella risk assessment carried out.
- The practice had a cleaning schedule in place that covered all areas of the premises and detailed what and where equipment should be used. We could not see evidence of national guidance on colour coding equipment to prevent the risk of infection spreading but

staff told us that the cleaner brought their own cleaning products and supplies. Staff were not sure whether there was a spillage kit available to clear up any spillage of blood or body fluids.

Equipment and medicines

- There were systems in place to check equipment had been serviced regularly, including the dental air compressor, autoclaves, fire extinguishers, oxygen and the X-ray equipment. We were shown the servicing certificates.
- An effective system was in place for the prescribing, administration and stock control of the medicines used in clinical practice such as local anaesthetics and antibiotics. These medicines were stored safely for the protection of patients. We found dental materials in the treatment room that had passed their expiry date and staff were not aware. The expired products were removed from the treatment room and we brought these to the attention of the practice manager. Staff disposed of these immediately.

Radiography (X-rays)

- We checked the practice's radiation protection records as X-rays were taken and developed at the practice. We found there were arrangements in place to ensure the safety of the equipment. We saw local rules relating to the X-ray machine were available.
- We found procedures and equipment had been assessed by an independent expert within the recommended timescales. The practice had a radiation protection adviser and had appointed a radiation protection supervisor.
- In order to keep up to date with radiography and radiation protection and to ensure the practice is in compliance with its legal obligations under Ionising Radiation (Medical Exposure) Regulation (IRMER) 2000, the General Dental Council recommends that dentists undertake a minimum of five hours continuing professional development (CPD) training During each five year CPD cycle. We saw evidence that the dentists were up to date with this training. The X-ray machine was not fitted with a rectangular collimator. Rectangular collimators decrease scatter radiation leading to improved image clarity as well as decreasing the amount of radiation the patient is exposed to. A dentist thought one was available but this could not be located.
- Dental care records we reviewed showed the practice was justifying, reporting on and grading X-rays taken. The practice had not carried out any audits to ensure the quality of radiographs.

Are community dental services effective? (for example, treatment is effective)

Monitoring and improving outcomes for patients

- The dentists told us they regularly assessed each patient's gum health and took X-rays at appropriate intervals. Dental care records showed a comprehensive examination of a patient's soft tissues (including lips, tongue and palate) had been carried out and the dentists had recorded details of the condition of patients' gums using the basic periodontal examination (BPE) scores. (The BPE is a simple and rapid screening tool that is used to indicate the level of examination needed and to provide basic guidance on treatment need). In addition they recorded the justification, findings and quality assurance of X-ray images taken.
- The dentists carried out an oral health assessment for each patient, which included their risk of tooth decay, gum disease, tooth wear and mouth cancer. The results were then discussed with the patient (and documented in the patient record) along with any treatment options, including risks, benefits and costs.
- The practice kept up to date with other current guidelines and research in order to develop and improve their system of clinical risk management. For example, the practice referred to National Institute for Health and Care Excellence (NICE) guidelines in relation to wisdom teeth removal and in deciding when to recall patients for examination and review.

Health promotion & prevention

- Staff we spoke with told us patients were given advice appropriate to their individual needs such as smoking cessation or dietary advice. This was also recorded in the dental care records we reviewed.

Staffing

- A trainee dental nurse said they had been shown what to do in the decontamination room by the registered manager but there were no protocols available to follow and there was a general lack of knowledge or

understanding about the processes. The practice could not provide evidence that staff had undertaken training to ensure they were kept up to date with the core training and registration requirements issued by the General Dental Council. This included areas such as responding to medical emergencies, safeguarding and infection control and prevention.

Working with other services

- Referrals for patients when required were made to other services. The practice had a system in place for referring patients for dental treatment and specialist procedures such as orthodontics and minor oral surgery. Staff told us where a referral was necessary, the care and treatment required was fully explained to the patient. There was a system in place to record and monitor referrals made to ensure patients received the care and treatment they required in a timely manner.

Consent to care and treatment

- The practice told us that staff ensured they obtained informed consent from patients for all care and treatment. Staff confirmed individual treatment options, risks and benefits were discussed with each patient who then received a detailed treatment plan and estimate of costs. We asked the dentists to show us some dental care records which reflected this. Patients were given time to consider and make informed decisions about which option they wanted.
- The Mental Capacity Act 2005 (MCA) provides a legal framework for health and care professionals to act and make decisions on behalf of adults who lack the capacity to make particular decisions for themselves. Staff had not received MCA training and they did not demonstrate a good understanding of the MCA and how this applied in considering whether or not patients had the capacity to consent to dental treatment.
- Staff members we spoke with were clear about involving children in decision making and ensuring their wishes were respected regarding treatment. They were familiar with the concept of Gillick competence regarding the care and treatment of children under 16. Gillick competence principles help clinicians to identify children aged under 16 who have the legal capacity to consent to examination and treatment.

Are community dental services caring?

Respect, dignity, compassion & empathy

- We observed all staff maintained privacy and confidentiality for patients on the day of the inspection. Practice computer screens were not overlooked in reception and treatment rooms which ensured patients' confidential information could not be viewed by others.
- We saw that doors of treatment rooms were closed at all times when patients were being seen. Conversations could not be heard from outside the treatment rooms which protected patient privacy.
- Dental care records were stored electronically and computers were password protected to ensure secure access. Computers were backed up and passwords changed regularly in accordance with the Data Protection Act.
- We did not see evidence for all staff in information governance training. Staff were confident in data protection and confidentiality principles.

Involvement in decisions about care and treatment

- The practice provided clear treatment plans to their patients that detailed possible treatment options and costs. Posters showing private treatment costs were displayed in the waiting area. The practice's website provided patients with information about the range of treatments which were available at the practice.
- We spoke with staff about how they implemented the principles of informed consent. Informed consent is a patient giving permission to a dental professional for treatment with full understanding of the possible options, risks and benefits. We looked at dental care records with clinicians, which confirmed this.

Are community dental services responsive to people's needs? (for example, to feedback?)

Responding to and meeting patients' needs

- We saw the practice waiting area displayed a variety of information including the practice opening hours and

treatment costs. Leaflets on oral health conditions and preventative advice were also available. Staff told us that every effort was made to see all emergency patients on the day they contacted the practice.

Tackling inequity and promoting equality

- The practice had an equality and diversity policy in place to support staff in understanding and meeting the needs of patients.
- The practice had made reasonable adjustments to prevent inequity to any patient group. The treatment room was accessible to patients with limited mobility and wheelchair users but the toilet was not. The patient information leaflet included a disability access statement which confirmed this clearly to patients. Staff would work with patients to seek a dental practice with full access as appropriate.

Access to the service

- The opening hours were displayed in their premises and on the practice website. Dental services were predominantly only available on Wednesdays but appointments could be arranged on other days of the week by prior arrangement.
- There were clear instructions on the practice's answer machine for patients requiring urgent dental care when the practice was closed.

Concerns & complaints

- The practice had a complaints policy which provided guidance to staff on how to handle a complaint. The policy was detailed in accordance with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 and as recommended by the GDC.
- Information for patients was available in the patient information leaflet. This included how to make a complaint. Staff told us they raised any patient comments or concerns with the practice manager immediately to ensure responses were made in a timely manner.
- The practice had not received any complaints in the last 12 months.

Are community dental services well-led?

Governance arrangements

- The practice manager provided us with the practice policies, procedures, certificates and other documents. We viewed documents relating to safeguarding, whistleblowing, complaints handling, health and safety, staffing and maintenance. We noted policies and procedures were not reviewed and updated appropriately to support the safe running of the service. Generic policies had been adopted which were not personalised to the practice. For example, there were gaps to insert the name of lead individuals, processes, up to date guidance and the location of equipment.
- The practice manager kept all staff files, training logs and certificates and ensured there were quality checks of clinical and administration work. The practice did not have an effective approach for identifying where quality or safety was being affected and addressing any issues. Health and safety and risk management policies and risk assessments were incomplete and systems were not in place to ensure that all staff were up to date with mandatory training.
- We looked at the Control of Substances Hazardous to Health (COSHH) file which contained detailed risk assessments for domestic cleaning substances used in the practice but no risk assessments had been carried out for any dental materials. The practice had carried out health and safety and fire risk assessments, each was in accordance with the relevant legislation and guidance.

Leadership, openness and transparency

- The overall leadership was provided by the registered manager. The ethos of the practice was clearly apparent in all staff as being able to provide the best service possible. Staff told us they were aware of the need to be open, honest and apologetic to patients if anything was to go wrong; this is in accordance with the Duty of Candour requirements.

Learning and improvement

- The practice did not carry out a programme of clinical audits. An audit is an objective assessment of an activity designed to improve an individual or organisation's operations. We discussed the requirement to audit the quality of X-rays and record keeping. An infection control audit had been carried out but this was undated and

referred to old guidance, in addition, a number of questions had been answered incorrectly. For example, questions relating to washer disinfectors and the dating of sterilised instruments.

Practice seeks and acts on feedback from its patients, the public and staff

- The practice had systems in place to seek and act upon feedback from staff members and people using the service. Staff and patients were encouraged to provide feedback on a regular basis either verbally or online. The practice also carried out their own survey with monthly analysis. Both survey results were displayed in reception to show patients how their views have been considered.
- Staff told us their views were sought and listened to and that they were confident to raise concerns or make suggestions to the practice manager.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take action to ensure staff have up to date statutory training.
- The provider must take action to monitor staff compliance with their health and safety policy.
- The provider must take action to ensure the clinical lead has current advanced life support training (ALS) to ensure compliance with best practice guidance.
- Staff members must receive the training they need to use the emergency resuscitation equipment.
- The provider must ensure they take action to ensure compliance with
- The provider must take action to ensure they undertake legionella assessments for water sources within the premises.
- The provider must ensure the safe and secure storage and disposal of medicines.
- The provider must identify a clear process for the identification and disposal of expired medicines.
- The provider must ensure that patients' undergo a comprehensive pre-assessment, which is documented within medical records.
- The provider must ensure the secure storage of patient records at all times.
- The provider must ensure that staff files are kept up to date with details of training and key competencies and these are reviewed regularly to ensure staff are still competent, qualified and suitably skilled to undertake the role they are employed in.
- The provider must ensure that staff are risk assessed where they have not had a vaccination for Hepatitis B, to ensure the safety of the staff and that staff are vaccinated as soon as is possible.
- The provider must take action to ensure consent is sought from patients before prescribing unlicensed medication.
- The provider must review the availability of medicines and equipment to manage medical emergencies giving due regard to guidelines issued by the Resuscitation Council (UK), and the General Dental Council (GDC) standards for the dental team.
- The provider must review the practice's safeguarding policy and staff training; ensuring it covers both children and adults and all staff are trained to an appropriate level for their role and aware of their responsibilities.
- The provider must review the arrangements for the control of legionella. Make arrangements for a legionella risk assessment to be carried out and implement the required actions including the monitoring and recording of water temperatures, giving due regard to the guidelines issued by the Department of Health - Health Technical Memorandum 01-05: Decontamination in primary care dental practices and The Health and Social Care Act 2008: 'Code of Practice about the prevention and control of infections and related guidance.
- The provider must review the system to risk assess the Control of Substances Hazardous to Health (COSHH) and ensure risk assessments for all dental materials used within the practice are implemented.
- The provider must review the practice's system for the recording, investigating and reviewing incidents or significant events with a view to preventing further occurrences and, ensuring that improvements are made as a result.
- The provider must review the practice's safeguarding policy and staff training; ensuring it covers both children and adults and all staff are trained to an appropriate level for their role and aware of their responsibilities.
- The provider must review staff awareness of the requirements of the Mental Capacity Act (MCA) 2005 and ensure all staff are aware of their responsibilities under the Act as it relates to their role.

Outstanding practice and areas for improvement

- The provider must review the practice's sharps procedures giving due regard to the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013
- The provider must review the protocol for completing accurate, complete and detailed records relating to employment of staff. This includes making appropriate notes of verbal reference taken, ensuring recruitment checks, including references, are suitably obtained and recorded and ensuring immunisation status are suitably obtained and recorded. Risk assessments should be carried out on clinical staff where immunity has not yet been assured.
- The provider must take appropriate actions to ensure staff working in the service receive an appropriate appraisal.
- The provider must take action to ensure there is appropriate oversight of prescriptions and they are audited regularly.
- The provider must ensure all staff understand how to report incidents, the location of the accident book and what constitutes an incident in relation to the their policy.
- The provider must ensure there is a documented two stage consent process and that patients' records reflect a 14 day cooling off period for cosmetic surgery procedures.
- The clinical lead must utilise best practice guidance in relation to liposuction procedures and surgical procedures as part of on going continued professional development and learning
- The provider must put a system in place to improve and review safety systems and processes and monitor the outcomes for learning purposes.
- The provider must ensure that all medications are appropriately stored.
- The provider must review stocks of dental materials and the system for identifying and disposing of out-of-date stock.
- The provider must review the practice's infection control procedures and protocols giving due regard to guidelines issued by the Department of Health - Health Technical Memorandum 01-05: Decontamination in primary care dental practices and The Health and Social Care Act 2008: 'Code of Practice about the prevention and control of infections and related guidance. This relates to the manual cleaning, inspection and storage of sterilised instruments.

Action the provider SHOULD take to improve

- The provider should review the practice's arrangements for receiving and responding to patient safety alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Agency (MHRA) and through the Central Alerting System (CAS), as well as from other relevant bodies such as, Public Health England (PHE).
- The provider should ensure staff use the World Health Organisation surgical safety checklist (or equivalent) to ensure appropriate checks prior to, during and following surgery.
- The provider should review the training, learning and development needs of individual staff members and have an effective process established for the on-going assessment and supervision of all staff, ensuring staff are up to date with their mandatory training and their Continuing Professional Development.
- The provider should review the practice's recruitment policy and procedures to ensure character references for new staff as well as proof of identification are requested and recorded suitably.
- The provider should review the practice's audit protocols of various aspects of the service, such as radiography and dental care records at regular intervals to help improve the quality of service. Practice should also check all audits have documented learning points and the resulting improvements can be demonstrated.
- The provider should ensure that they update their policies and procedures in line with best practice guidance and review where incorrect information has been highlighted.
- The provider should ensure staff know the location of a spillage kit for body fluids and how to use it, if necessary.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider failed to ensure there were effective systems in place to ensure the same care and treatment of service users. We issued warning notices to the provider and registered manager to address these issues.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider failed to have effective systems and processes in place to ensure there was appropriate governance and managerial oversight of the clinic. There was no evidence of audits including an absence of records audits, monitoring of patient outcomes audits and evidence of improvement to the quality and safety of the services provided. We issued warning notices to the provider and registered manager to address these issues.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing The provider failed to provide any evidence of staff competency to undertake key aspects of their roles.

This section is primarily information for the provider

Enforcement actions

We issued warning notices to the provider and registered manager to address these issues.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed There was no evidence of a clear recruitment policy or referencing process for four staff members employed at the time of our inspection. We issued warning notices to the provider and registered manager to address these issues.