Wimpole Aesthetic Centre

Quality Report

48 Wimpole Street
Marylebone
London
W1G 8SF
Tel: 020 7224 2247
Website: www.wimpoleaesthetics.co.uk

Date of inspection visit: 28 March 2017
Date of publication: 16/08/2017

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

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

Wimpole Aesthetic Centre (WAC) is operated by Wimpole Aesthetic (Medical) limited. The hospital has no inpatient beds. Facilities include an operating theatre, treatment rooms (one of which was used for laser treatments) and a reception area.

The hospital provided cosmetic surgery and non–regulated cosmetic treatments to adult patients.

We inspected this service using our comprehensive inspection methodology on 28 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.

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.

During our inspection we found significant concerns, and the provider needed to improve in a number of areas. This included staff recruitment and training, governance arrangements relating to other medical professionals working at the service, infection prevention and control, and adherence to surgical safety protocols, including the World Health Organisation surgical safety checklist. They also needed to make improvements with regard to the management of medicines.

Following this inspection, we told the provider that it must take some urgent actions to comply with the regulations. They were asked to make other improvements to the service, even though a regulation had not been breached. Details are at the end of the report. Following our inspection we took the unusual step to suspend the regulated activity of surgery until further notice because of our concerns about patient safety.

On 28 June 2017, the Head of Inspection (London South Acute Hospitals), a CQC inspector and a specialist advisor returned to the hospital to conduct an announced focused inspection. We are able to report the hospital had made significant improvements in all areas previously of concern.

However, we found the process for the decontamination of surgical instruments was contrary to best practice, government issued guidelines and the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance. As a result we issued a warning notice requiring the provider become compliant by 4 August 2017. Full details can be found at the end of this report.

Taking the areas of improvement into account we were sufficiently assured regarding patient safety to lift the suspension of the regulated activity of surgery. We will return to conduct a further focussed inspection in the near future to ensure the provider continues to meet the requirements of the HSCA and associated regulations.

Professor Edward Baker

Chief Inspector of Hospitals

Summary of findings

Contents

Wimpole Aesthetic Centre

Services we looked at
Surgery

Summary of this inspection

Background to Wimpole Aesthetic Centre

Wimpole Aesthetic Centre (WAC) is operated by Wimpole Aesthetic (Medical) limited. The clinic is a small independent hospital offering cosmetic surgery services to private patients. The clinic occupies a basement level, which encompasses the operating theatre, treatment rooms and a reception area. There are also consulting and administration rooms. There were no inpatient beds at the clinic. No surgical procedures are carried out on young people under the age of 18.

Wimpole Aesthetic Centre has been operating since 2007 and the registered manager has been registered with the commission since October 2010.

We inspected Wimpole Aesthetic Centre as part of our schedule for independent hospital. The hospital was last inspected by the CQC in December 2012 when it was assessed to have met the standards of quality and safety we expect.

Our inspection team

The team inspecting the service comprised a CQC lead inspector,another CQC inspector, and a specialist advisor with expertise in theatre practice. The inspection team was overseen by Nick Mulholland, Head of Hospital Inspection (London South).

How we carried out this inspection

To understand the patients' experiences of care, we always ask the following five questions of every service and provider:

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

We analysed information we held on the service prior to our inspection. We carried out an announced onsite inspection on 28th March 2017, where we observed practice and spoke with five members of staff. We also reviewed nine sets of records for patients treated at WAC, received feedback from nine patient Care Quality Commission comment cards and reviewed other documents requested during the visit.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

Wimpole Aesthetic (Medical) Limited trading as Wimpole Aesthetic Centre is a private medical practice, which provides cosmetic surgical and non-surgical treatment for a variety of conditions. Services are provided only to adults, and include minor surgery for various lumps and bumps (warts, lipomas, sebaceous cysts and revision of scars), and liposuction under local anaesthetic and conscious sedation.

The hospital is registered to provide the regulated activities:

- Surgical procedures
- Treatment of disease, disorder or injury

The registered manager (RM) is the medical director and the practising consultant at the location. He has been registered as the RM with the Commission since October 2010.

The hospital employed one registered nurse, a nursing assistant, a business manager, a patient co-ordinator and a receptionist.

The on-site surgical procedures were carried out under local anaesthetic or conscious sedation.

There were over 570 attendances in the reporting period October 2015 to September 2016. Between January and August 2016, the hospital performed 131 surgical procedures including 37 liposuction procedures.

During our inspection process we spoke with the RM and his staff (clinical and administrative).

Summary of findings

There were no formal arrangements to assure us that systems or processes had been established and were operating effectively with regard to persons employed in the carrying on of the regulated activity of surgery.

There was a lack of evidence to indicate the recruitment processes were robust, and that appropriate checks had been carried out with regard to staff's suitability to undertake their required activities. We were not provided with satisfactory checks, including documentary evidence of any qualifications relevant to the duties for which the staff were employed or appointed to perform.

We were not provided with any evidence to demonstrate staff employed for the purpose of providing the regulated activities had received appropriate support, including relevant mandatory safety and safeguarding training.

Practising privileges were not in evidence for medical personnel undertaking duties associated with the regulated activities.

There was no evidence of the oversight of ongoing competence of doctors in that there was no formal policy detailing how doctors' competencies should be monitored by the nominated individual.

There was no effective system in place to demonstrate the competence of anaesthetists administering conscious sedation was assessed and was monitored to ensure they were carrying out their practice in line with national guidance.

Surgery

There was no evidence to demonstrate that staff working at Wimpole Aesthetic Centre had the appropriate qualifications, competencies, skills and experience associated with the regulated activities.

There was no formalised incident reporting process, and as a result staff were not aware of what constituted an incident or how to report an incident. There was no process for investigating or acting on the findings, and no evidence of learning from incidents.

There was a lack of a robust medicines management process related to the storage of medicines, controlled drugs recording and prescription pads. In addition, a non-qualified member of clinical staff was undertaking cannulation and administering medicines, without having had cannulation training or medicines administration training.

The infection prevention and control practices did not adhere to The Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance, with regard to sterilisation processes, and single use items were being re-used. Safety checks on sterilisation equipment, cleaning of equipment used by patients, and cleaning of the patient environment between patients was not supported by relevant guidance or monitoring.

Emergency procedures were not fully established with regard to immediate resuscitation and transfer of patients. There was no policy to guide staff with regard to the management of deteriorating patients, or what process to follow when they were caring for patients post-surgery.

There was a lack of reference to professional guidance with respect to caring for the patient, including; no adherence to the World Health Organisation (WHO) Surgical safety checklist, intra-operatively, and post-operatively. There was no formal tool for assessing and recording a patient's physiological status as a means of determining early signs of possible deterioration.

There were no formalised governance processes, risk management or auditing to determine the safety and effectiveness of its services.

Are surgery services safe?

Incidents

- The Wimpole Aesthetic Centre (WAC) reported there were no never events for the period October 2015 to September 2016.
- WAC reported one incident in the reporting period October 2015 to September 2016, although none of the staff we spoke with could recall what the clinical incident was. However, one member of staff described cutting their finger when breaking a medicine vial but did not report it. We neither saw nor were we shown evidence of a formalised incident reporting process, and as a result staff we spoke with were unclear about what constituted an incident or how to report one. There was no evidence of a process for investigating or acting on the findings, and no evidence of learning from incidents.
- From November 2014, NHS providers were required to comply with the duty of candour (regulation 20) of the Care Quality Commission (Registration) Regulations 2014. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- Being open / duty of candour was part of the WAC's training programme; although at the time of the inspection none of the staff had completed this training. One member of staff we spoke with was able to explain satisfactorily her understanding of duty of candour.

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

- The WAC unlike NHS trusts is not required to use the national safety thermometer to monitor areas such as venous thromboembolism (VTE) or pulmonary embolism (PE). However, the National Institute for Health and Care Excellence (NICE) recommends all healthcare professionals follow the quality standard in the clinical guideline CG138.

Cleanliness, infection control and hygiene

Surgery

- No surgical patients were tested for meticillin-resistant Staphylococcus Aureus (MRSA) prior to surgery. This was not in line with the Department of Health (2014) Implementation of modified admission MRSA screening guidance for NHS (2014).
- The infection prevention and control practices did not adhere to The Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance. Whilst all clinical areas we inspected were visibly clean, we found the theatre was cluttered. We saw there were daily cleaning schedules. However, we found there were no clear procedures in the theatre or clinical rooms for instructing staff as to expectations for cleaning equipment between patients, and no records were completed to indicate such cleaning took place. There was a risk that equipment was not sufficiently clean or prepared for the next patient's use.
- There was access to personal protective equipment (PPE) such as gloves and alcohol hand sanitising gel was available.
- Hand wash basins were available in each patient's room. Hand gels were also available at the entrance and in common areas on the wards and theatres. There were no surgical patients at the hospital during our inspection and we did not witness staff utilising hand hygiene facilities.
- WAC had an infection prevention and control (IPC) assessment undertaken by an external provider in February 2017. At the time the overall compliance rating was found to be 75%. The areas of non-compliance included hand wash sinks in treatment and clinical rooms were not Health Technical Memorandum (HTM) 64 compliant – mixer taps were not wrist /elbow operated. Spillage kits were not available in all treatment areas, and there was evidence single use items had been sterilised and repackaged. During the inspection we found these issues had not been addressed.
- Infection control was part of the WAC's training programme. At the time of the inspection none of the staff had attended infection control training.

Environment and equipment

- The Intravenous (IV) and clinical rooms were carpeted, which posed an increased IPC risk over seamless clinical flooring. The IV room also had no sink and the trolley which held IV glucose, plasters, and cannulas was easily accessible to non-authorised persons.
- The electrical equipment safety testing certificate was valid until April 2017.
- A defibrillator, used to re-start a patient's heart, was accessible in the theatre and this was checked once a month. However, we found equipment, including ambu-bags, were not in sealed bags and there were no filters for the ambu-bags. WAC was unable to tell us if the ambu-bags were in date and effective for use.
- The service contract for the steriliser had expired in September 2016, which meant WAC was unable to guarantee sterilisation of any instruments was to specification. We found several items (scissors, forceps, clamps,) marked as single use which had been sterilised for use after the marked sterile expiry date and one item (a probe) with a date of 2015 was available to be used. The IPC assessment undertaken by an external provider in February 2017 stated 'items are currently sterilised on site, however the process is not fully HTM 2010 compliant.' The RM told us all instruments were sterilised every three months, this was not evidenced during our inspection. The re-sterilisation of single use surgical instruments in any form is not considered best practice although it is the subject of debate within the health community.
- We found the laser protection policy was out of date; WAC was unable to evidence any laser safety training or updates for the staff using the laser. We found the laser warning light was not operational; this meant there were no evidence of arrangements in place to control and restrict access to the laser to indicate when the rooms and lasers were in use. This was not in compliance with the Medical and Healthcare products Regulatory Agency (MHRA) guidance. In our view this indicated laser safety was not a priority to the provider and this posed a potential risk to patients and staff.
- Health and safety was part of the WAC's training programme. At the time of the inspection none of the staff had attended health and safety training.

Medicines

Surgery

- WAC had a policy for medicines, which stated 'medicines would only be stored in locked cupboards or a locked pharmacy fridge within the treatment room'. We found prescription only medicines held in the treatment room were not stored securely to prevent unauthorised access.
- WAC policy for controlled drugs (CD's) stated 'It was the policy of Wimpole Aesthetic Clinic that no schedule 2 controlled drugs are used on the premises.'In one patient record we found evidence of Fentanyl (a schedule 2 controlled drug) had been used during conscious sedation. We were told the CD had been brought in and administered by a visiting anaesthetist who did not have practising privileges.
- In five patient records we saw conscious sedation had been administered by intravenous (IV) local injection, however it was not clear who had administered the drug, as records were not signed.
- Pharmacy fridges were locked and temperatures were checked daily and recorded. However, we saw the temperatures were not recorded accurately with accurate maximum, minimum and current temperature recorded. Staff we spoke with were unclear of what action they should take should the temperatures go out of range. One member of staff we spoke with was not aware the medicines held had to be stored at a cool temperature. The medicines stored in the fridges indicated they needed to be stored between 4 – 8 degrees.
- Medication was prescribed by the RM, however we found blank prescription pads were not stored securely and there was no system in place to record or log the usage of prescription pads.This did not meet best practice guidelines for the storage of drug stationery and meant there was a risk of these being stolen and misused.

Records

- We looked at nine sets of surgical patient notes relating to patients treated at WAC. The records were paper based and were legible, signed and dated.
- We saw allergies and results from blood tests were recorded.
- We saw no record that patients having elective surgery had been screened for Meticillin-resistant Staphylococcus Aureus (MRSA) and VTE. The RM confirmed they did not undertake these tests.
- Records were kept securely but readily available for use.

Safeguarding

- WAC had a policy for the protection of vulnerable adults.
- Two members of staff, one of whom was clinical, had limited understanding of the potential signs of abuse and the process for raising concerns. None of the five staff we spoke with were clear about the process to follow for reporting and who to report to.
- At the time of the inspection WAC was unable to provide evidence staff had received training in safeguarding adults since they had started working at the WAC.

Mandatory training

- At the time of the inspection WAC was unable to provide details of staff training, staff we spoke with told us they did not receive mandatory training and were not aware of the mandatory training they would need. Personnel records we looked at also confirmed this.
- However, WAC had a policy for training and continuing professional development which included general training for all staff and specific training for staff involved directly with patient care**.**
- The general training was defined as fire safety, health and safety, complaints management and WAC policies, protocols and procedures**.**
- Specific training included manual handling; core knowledge of laser safety, specific manufacturer approved training medical devices or equipment, infection control, being open/duty of candour.
- The lack of mandatory training would make it difficult for the hospital to be assured their staff were both competent and confident in the care they provided which could impact upon patient safety.

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

Surgery

- Patients having elective surgery were not screened for MRSA when they attended a pre-admission clinic. This meant that the patients may be at risk of becoming infected and there was also a risk that other patients may become infected.
- Patients did not have an assessment undertaken with regard to the risk of developing a venous-thromboembolism (VTE).
- All patients underwent tests before being accepted for surgery; full blood count and an erythrocyte blood test for inflammatory activity.
- Theatre staff did not use a surgical checklist based on the World Health Organisation (WHO) guidance. The RM advised they did not need to use it. We looked at nine sets of surgical patient records and there was no evidence of a surgical check list held on file.
- In this hospital all of the surgical procedures were completed by the RM assisted by directly employed staff with the exception of an anaesthetist brought in occasionally to assist with certain procedures.
- During our inspection we saw no evidence patients' clinical observations were recorded and monitored in line with the NICE guidance (CG50) 'Acutely Ill-Patients in Hospital. The Royal College of Surgeons recommends the use of the National Early Warning Score (NEWS), a tool based on physiological observations such as temperature, blood pressure and level of consciousness. The resulting observations are compared to a normal range to generate a single composite score as an aid to the identification of deteriorating patients.
- Surgical procedures carried out on-site were performed under local anaesthetic or conscious sedation. In one patient record we saw a visiting anaesthetist administered conscious sedation. Conscious sedation is defined as 'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely'. There was no practising privileges information regarding the anaesthetist used and no evidence of qualifications or practice could be provided other than a referral to the person's website. This meant we were unable to assure ourselves patient safety was not compromised.
- WAC did not provide high dependency, intensive or overnight care. In an emergency situation the standard 999 system was used to facilitate the transfer of the patient to an NHS hospital.
- WAC had a policy for resuscitation which stated 'at least one member of staff with immediate life support (ILS) will be on duty at all times when patients are on the premises'. At the time of the inspection WAC was unable to provide details of staff certified in immediate life support (ILS).

Nursing and support staffing

- We reviewed four personnel files and found robust recruitment checks had not been undertaken prior to employment, and appropriate checks had not been carried out to ensure staff had the qualifications for their position. For example, not all the records had proof of identification, references, evidence of qualifications, details of registration with a professional body, and the appropriate checks through the Disclosure and Barring Service (DBS) which was in breach of Schedule 3 of the Health and Social Care Act 2008.
- We found one health care professional undertaking procedures at WAC whose indemnity insurance had expired in February 2017. The WAC policy for training, experience and qualifications of staff states 'Nursing staff or other health care professionals undertaking procedures within Wimpole Aesthetic Centre must carry indemnity insurance'.
- WAC had a small tight-knit team, with low staff turnover. WAC did not use any bank or agency staff. Their small surgical list allowed them to list procedures to suit patient's needs and staff availability. The RM was normally supported by a nursing assistant when undertaking surgical procedures.

Medical staffing

- The surgical procedures were carried out by the RM assisted by the hospital staff and an anaesthetist when required. Although WAC had a policy for practising privileges in place the RM told us none of the visiting doctors or the anaesthetist who undertook work at WAC

had practising privileges. We reviewed two personnel records of visiting medical practitioner's personnel files associated with the other activities. We found pre and post-employment checks associated with practising privileges were not in place. This meant medical practitioners were operating without practicing privileges. The granting of practising privileges is a well-established process within independent healthcare whereby a medical practitioner is granted permission to work in an independent hospital or clinic, or in independent private practice**.**

- There was no formal policy or effective system detailing how a doctor's competencies should be monitored to ensure they were carrying out their practice in line with national guidance.

Emergency awareness and training

- Fire risk assessment should be undertaken annually. We saw WAC's last fire risk assessment was in June 2015. WAC did not have written procedures for emergency evacuation. However, staff we spoke with were aware of how they would exit the premises and where to assemble in the event of an emergency.
- Fire safety was part of the WAC's training programme. At the time of the inspection none of the staff had attended fire safety training.
- WAC had a policy in place for disruption to services. This included disruption to the electricity supply, gas supply and water supply. The policy stated patients would be contacted to advise them not to attend the Wimpole Aesthetic Centre. The policy also stated 'where necessary, emergency lighting will be used to ensure that any procedure is safely stopped and the patient made safe and comfortable'. However, there was no back-up generator to power the lights or equipment in the event of a loss of electrical supply which meant patient safety could have been compromised if the power failed during a procedure.

Are surgery services effective?

Evidence-based care and treatment

- WAC policies were available and staff we spoke with were aware of how to access these policies. We looked at a sample of policies saw these had been issued in January 2017 and were due for review in January 2018. The policies had been provided by an external provider. However, it was not clear if the policies were based on current best practice from a combination of national and professional guidance such as NICE and Royal College guidelines. The policies did not reference NICE or Royal College guidelines.
- We found no evidence NICE guidance was being followed and staff we spoke with were unable to provide such evidence. For example, surgical patients who had conscious sedation should be monitored for Hypothermia (NICE CG 65), with their temperatures measured and documented before induction of anaesthesia, and then every 30 minutes until the end of surgery and post operatively every 15 minutes. In patients' notes we found no documentation showing these observations had been undertaken. In the theatre we did not see any aural, skin or axillary probes for temperature monitoring.
- There was no evidence of there being a process or guidance for staff with regard to recognising and responding to deteriorating patients (NICE CG 50).
- WAC told us they undertook local audits on consent and the medical register. However, they were unable to produce this information when requested prior to and during the inspection.

Pain relief

- Prescribed local and conscious sedation medication was administered for effective pain relief during the procedure. However we saw no evidence that pain relief was assessed.
- We saw evidence of patients being given 'take home' pain relief medication and instructions for its use.
- We were told the RM or a member of his staff would discuss post-op medication and after care with the patient before left the hospital. We were unable to corroborate that directly from patients but those who completed our comment cards wrote positively about the service and the care they had received.

Nutrition and hydration

- The centre provided water, tea and coffee to all patients.
- The procedures undertaken at the centre did not require patients to fast beforehand.

- We saw no evidence of patients being monitored for hydration during lengthy operations.

Patient outcomes

- The centre had completed 131 surgical procedures in the reporting period October 2015 to September 2016, of which 37 were liposuction procedures. Information provided showed there were no returns to theatre and no re-admissions during this time.
- The Royal college of Surgeons has requested providers of cosmetic surgery to submit Q- Patient Reported Outcome Measures (PROMs) for cosmetic surgery procedures such as liposuction (Body-Q). PROMs are distinct from more general measures of satisfaction and experience, being procedure-specific, validated, and constructed to reduce bias effects. The data gathered from the use of PROMs can be used in a variety of ways to empower patients, inform decision making and, where relevant, support quality improvement. WAC did not collect or submit Q-PROMS data.
- At the time of our inspection WAC had not engaged with the Private Healthcare Information Network (PHIN) in accordance with the Private Healthcare Market Investigation Order 2014 regulated by the Competition Markets Authority (CMA).
- Staff told us in order to demonstrate positive outcomes for patients with their consent photos were taken before and after treatment. This is not sufficient to measure clinical outcomes.

Competent staff

- The RM was the only consultant at the hospital. He told us he attended conferences to keep his skills updated, and staff told us he attended peer group meetings with other local practice managers once a month to keep himself abreast of what was going on locally. His personnel file showed he attended conferences in 2015 and 2016. However, there were no records of the RM having undertaken recent training in the use of the laser, intermediate life support (ILS), infection control, or manual handling. The RM advised he had been appraised in December 2016, although we were not shown evidence of that.
- None of the staff we spoke with had ever had an appraisal or received regular supervision. WAC's self-assessment for resource and staff management completed in January 2017 indicated staff appraisals were to be introduced in 2017.
- One member of staff told us they were part way through an online training Care Skills course and another member of staff told us they had registered but were yet to start care skills training.
- WAC were unable to provide evidence checks were undertaken on staff's professional registrations, fitness to practice and validation of qualifications. One member of staff we spoke with was due to be revalidated in late 2017 but was not aware of the revalidation process for registered nurses.
- We found a member of staff who was a registered nurse and was undertaking regular cannulation of patients without having been trained to do so. When this was raised with the RM he was not aware staff should be trained and their competence assessed regularly.
- WAC policy for training, experience and qualification of staff stated all clinical staff must undertake an annual update in training for cardiopulmonary resuscitation (CPR) appropriate to their level of clinical responsibility and staff would participate in a six monthly simulation exercise for CPR. WAC were unable to provide details of staff CPR training.

Multidisciplinary working

- We saw no evidence in patient records of multidisciplinary team (MDT) assessments having been undertaken for patients who were day cases. However, WAC used the services of visiting anaesthetists and physicians.
- Staff told us they had a staff meeting once a month. Staff were not sure if the meetings were minuted as minutes were not circulated. We asked for copies of any minutes but none were provided.

Access to information

- Staff were able to access WAC policies and procedures.
- Patient records were stored securely on site and staff were therefore able to access records at any time. We did not see any diagnostic or imaging results in the records we examined.

Surgery

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- WAC did not provide Deprivation of Liberty Safeguards (DoLS) principles and the Mental Capacity Act (2005) training or dementia awareness training; staff we spoke with assumed the RM would pick such things up during his consultations. The RM explained they did not provide treatments for patients with a cognitive impairment.
- We saw consent forms were competed in the nine patient records of patients undergoing surgical procedures.However, we saw no evidence verbal consent was recorded in patient records.
- We were told patients were given sufficient time to consider cosmetic procedures before the surgery took place. The hospital's policy stated patient's consent "shall consist of … an adequate period for reflection and consideration and cosmetic surgery procedures will not take place on the same day as the consultation".
- The General Medical Council (GMC) in their 'Guidance for doctors who offer cosmetic interventions' gives the following guidance; "24. You must give the patient the time and information they need to reach a voluntary and informed decision about whether to go ahead with an intervention. 25. The amount of time patients need for reflection and the amount and type of information they will need depend on several factors. These include the invasiveness, complexity, permanence and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention. 26. You must tell the patient they can change their mind at any point."
- We saw consent forms had been completed and signed by the patient and the RM.

Are surgery services caring?

Compassionate care

- All of the nine patient Care Quality Commission comment cards we received were positive about the service experienced. Patients said they felt the practice offered a very good service and staff were helpful, caring and treated them with dignity and respect. There were no patients to speak with or observe on the day of the inspection.

Understanding and involvement of patients and those close to them

- If patients required clinical advice, either a consultation or a telephone conversation was arranged with the RM.
- Treatment fees for were discussed at the initial consultation and followed up in a letter with the patient.

Emotional support

- Patients were offered the opportunity to have a friend or relative present during consultations. The centre had notices on display which advised patients that chaperones were available.

Are surgery services responsive?

Service planning and delivery to meet the needs of local people

- WAC provided cosmetic procedures to adults over the age of 18 years. Only procedures which did not require general anaesthesia were performed at the hospital.
- WAC provided private elective surgery, admissions were planned in advance at times to suit the patients.
- None of the procedures carried out at the hospital involved an overnight stay. Staff told us they would call the emergency services if a patient unexpectedly required it. The centre had no written emergency procedure in place to deal with such emergencies.
- WAC was open Monday to Friday from 9.30am to 6pm and on a Saturday by appointment.

Access and flow

- The WAC did not routinely contact a patient's GP. Staff told us for some non-surgical procedures they would contact a patient's consultant, if for example they had cancer, for permission to go ahead.
- There were 131 surgical procedures undertaken between October 2015 and September 2016. These procedures were for removal of various skin lesions 72%

(94) and Vaser liposuction 28% (37), of those nine were cancelled due to non-clinical reasons. These were rearranged with the patient for the earliest convenient time.

- Patients could access the service in a timely way.

Meeting people's individual needs

- The multicultural makeup of the WAC staff meant they were able to converse with patients in a number of different languages. Arrangements could be made for formal translation and interpreting services.
- The basement location of WAC at 48 Wimpole Street meant patients with restricted mobility could not access it.
- We were told all potential surgical clients had a consultation with the RM, part of which was an assessment of their medical conditions, if any. Any contraindications would be explained to the client and the proposed procedure would not go ahead.

Learning from complaints and concerns

- WAC had a policy for handling complaints and concerns. The policy stated complaints would be acknowledged within two working days and a full response would be made within 20 working days of receipt. Where this time frame was not possible then a letter would be sent to the complainant and a full response would be sent within five working days of the conclusion of the process.
- Data provided by WAC showed there was one complaint between October 2015 and September 2016.
- The policy did not identify who was responsible for the management of the complaints process. WAC was unable to provide evidence of action plans or shared learning from the complaint.
- Patient information was available on how to raise a concern; however information within the leaflet did not reflect WAC's policy and referred patients to NHS England. This was not the most appropriate advice as they were not NHS patients. WAC was not a subscriber to the Independent Healthcare sector Complaints Adjudication Service (ISCAS).

Are surgery services well-led?

Leadership / culture of service related to this core service

- Staff told us they see each other during the working day and the RM had an 'open door' policy. They felt supported and enjoyed working there.
- Staff told us they would direct any concerns about a patient to the RM to be dealt with.
- There was a staff meeting once a month; however staff we spoke with were unsure if the meeting was minuted as minutes were not circulated.

Vision and strategy for this core service

- Prior to our inspection the hospital provided the following vision and strategy statement, "The vision and strategy of this clinic is to see the patient numbers grow by both the acquisition of new patients and the retention of those we already have. The clinic will continue to be innovative, acquire new equipment and treatments provided they are safe and efficacious. It is hoped that the clinic will team with new branches and new colleagues so that perhaps in the next few years there will be five or six locations."
- Staff we spoke with were not able to tell us what the vision and strategy was for the WAC. However, staff told us they wanted to see WAC flourish and grow.

Governance, risk management and quality measurement (and service overall if this is the main service provided)

- WAC did not have a clear and robust governance structure in place. There were no formal processes in place to improve patient safety, to learn from patients' experience, improve clinical effectiveness and the patient experience.
- WAC did not have a medical advisory committee (MAC).It is usual practice for the MAC to advise the registered person on matters relating to the granting of practising privileges, clinical standards, new and emerging professional guidance, the introduction of new treatments and capital investments. This meant there was no formal system for medical staff at the service to ensure that that practice, policies and procedures met current guidance and best practice.

Surgery

- WAC did not have a formal risk register. A risk register is a management tool which enables an organisation to understand its risk profile, as risks are logged on the register and action taken to respond to the risks. This meant the management team were not sighted to potential risks at the service, had no formal system to assess and review these risks and plan and implement appropriate mitigations.
- WAC did not have effective systems in place for recruitment and selection of staff which ensured appropriate recruitment checks had been undertaken prior to employment. This mean there was a risk that patients could be treated by staff who did not have the necessary qualifications, skills and experience to carry out their jobs safely, or be of good character.

Public and staff engagement

- WAC engaged with the public on social media including Facebook, YouTube and twitter, there was also a 'blog' about treatments that were available,
- Patients were able to leave feedback via the WAC website. We saw no evidence of how this was used to inform how the service was run or could improve.
- Staff told us being such a small team their communication was good and they felt able to have their say and get feedback.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Introduce formal arrangements which ensure safe and effective systems or processes are established and are operating effectively with regard to persons employed in the carrying on of the regulated activity.
- Introduce formal arrangements which ensure the recruitment processes are robust, and that appropriate checks are carried out with regard to staff's suitability to undertake their required activities.
- Introduce formal arrangements which ensure staff employed for the purpose of providing the regulated activities have received appropriate support, including relevant mandatory safety and safeguarding training.
- Introduce formal measures which ensure robust governance arrangements are in place for medical professionals working under practising privileges.
- Introduce formal arrangements for robust governance arrangements are in place which ensure staff working at Wimpole Aesthetic Centre have the appropriate qualifications, competencies, skills and experience to carry out the regulated activities.
- Introduce arrangements which ensure a formalised incident reporting process together with processes for investigating, acting on the findings and learning from incidents has been established.
- Introduce measures which ensure robust governance arrangements and medicines management processes related to the storage of medicines, controlled drugs recording and prescription pads has been established.
- Introduce formal arrangements which ensure infection prevention and control practices at the Wimpole Aesthetic Centre comply with the Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance.
- Introduce arrangements which ensure robust emergency procedures were established relating to the immediate resuscitation and transfer of deteriorating patients.
- Introduce arrangements which ensure national guidance is being followed relating to patient care including adherence to the World Health Organisation (WHO) Surgical safety checklist, intra-operatively and post-operatively.
- Introduce arrangements which ensure patients' physiological status is assessed and recorded according to national guidance as a means of determining early signs of possible deterioration.
- Introduce measures which ensure robust governance and management processes are in place to determine the safety and effectiveness of its services by means of regular auditing.
- Introduce measures which ensure robust governance and management processes for the testing of patients for VTE and MRSA in line with NICE guidance CG92, CG138 and Department of Health best practice guidance have been established.
- Update the laser policy in line with the latest guidance and regulations including the Medical and Healthcare products Regulatory Agency (MHRA) guidance and ensure any staff training is undertaken and properly recorded.

Action the provider SHOULD take to improve

- Consider introducing a comprehensive hospital risk register capable of recording identified risks, dates, actions and outcomes.

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
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The registered manager described the process by which decontamination of surgical instruments was undertaken. The registered manager described the following process: Surgical instruments entered the decontamination area by way of an open entrance hall. This entrance was not compliant with national guidance in that there was no separate "Dirty in, Clean out" entrance or exit. The registered manager informed us that surgical instruments would first be washed in an approved cleaning solution and then rinsed in separate sinks. The surgical instruments were then subject to approximately four or five cycles in a sonic washer before being allowed to air-dry. Once dried, the registered manager informed us that surgical instruments were placed in plastic storage boxes, sprayed with a solution called Q-Shield and then stored in a cupboard in the clinical treatment room. The registered manager informed us that surgical instruments were not subject to autoclaving until they were next required for a surgical procedure. The described process was contrary to best practice, government issued guidance and the Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance. When asked whether the process and decontamination area had been subject to a risk assessment or other assessment to determine compliance with nationally set standards, the registered manager confirmed that no such risk assessment or other documentation existed. You are failing to comply with Regulation 12(1)(2)(e)(h): safe care and treatment of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

This section is primarily information for the provider

Enforcement actions

You are required to become compliant with Regulation 12, section (1)(2)(e)(h), of the

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 above by 18 August 2017. Please note: If you fail to achieve compliance with the relevant requirement within the given timescale, we may take further action.