Aesthetic Beauty Centre - Newcastle-upon-Tyne

Quality Report

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

Overall summary

We carried out a focussed unannounced inspection on 12 June 2017. The inspection was in response to concerns relating to the effectiveness of processes to ensure that surgeons with practicing privileges were not undertaking procedures outside their level of expertise. We inspected the Aesthetic Beauty Centre and looked at whether the service was safe, effective, and well-led.

Although we regulate cosmetic surgery services, 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 areas that the provider needed to make improvements. This included governance arrangements to ensure that systems captured information about all categories of risk and identified the action to improve, and to ensure systems were in place for the safe storage, security and recording of medicines.

Following this inspection, we told the provider that it must take some 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.

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

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Summary of this inspection

Background to Aesthetic Beauty Centre - Newcastle-upon-Tyne

Aesthetic Beauty Centre LLP operated the Aesthetic Beauty Centre. The clinic had no inpatient beds. Facilities included an operating theatre, consultation and treatment rooms one, of which was used for laser treatments and a reception area.

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

Our inspection team

Our inspection team was:

Inspection Lead: Helena Lelew, Inspection Manager, Care Quality Commission

The team included another CQC inspector, a doctor in cosmetic surgery and a registered theatre nurse.

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 carried out a focussed unannounced inspection on 12 June 2017, where we observed practice and spoke with five members of staff. We also reviewed five sets of patient records and looked at policies and procedures.

Detailed findings from this inspection

Surgery

Safe	
Effective	
Well-led	

Information about the service

The Aesthetic Beauty Centre is an independent clinic offering cosmetic treatments to day-patients using a range of non-invasive or minimally invasive procedures including laser and non-laser technology and treatment techniques. These include blepharoplasty, facelift, breast augmentation, and abdominoplasty. The number of surgical procedures average 300 per year. The majority of these are liposuction. The surgical procedures are carried out under local anaesthetic or conscious sedation.

The patient profile is diverse but predominately healthy.

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

The aesthetic surgeon and registered nurse are the directors and manage the service. Staffing includes an agency theatre nurse, and an anaesthetist with practicing privileges, a non-registered nurse, and a number of administrative staff.

The Aesthetic Beauty Centre was registered with the Commission in 2010 and the manager has been registered since 2011.

Summary of findings

Although there was an incident reporting system, staff we spoke with during the inspection were not aware of how to report an incident and were not clear how to identify when an incident had occurred. Governance arrangements to capture information about all categories of risk to monitor and manage quality and performance and to identify the action taken to improve required strengthening. This included clinical, internal and external audit.

Swabs and equipment were counted verbally between the operating surgeon and scrub nurse prior to and after surgery, however at the time of inspection the counts were not documented formally. The provider has since the inspection ensured that the counts are written formally and are confirmed on completion.

The systems for medicines management did not always ensure safe storage, security and recording. Since the inspection, the provider has rectified this to ensure that the medication cupboard was lockable and that the amount of medication given and wasted was recorded in the Controlled Drugs Book.

Although we were told that equipment such as the resuscitation trolley was checked weekly there was no evidence to show it was being formally documented. The manager showed us a book, which they planned to start using to document equipment checks.

Staff had received appropriate training however, information was stored in individual personnel files, which did not provide managers with an overall or immediate oversight of who had completed what training, and when it was next due. The manager was developing a system to capture this information.

The policies were based on relevant evidence-based guidance, best practice, and legislation, including the National Institute of Health and Care Excellence (NICE) and other professional bodies. However, it was not clear

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how the service assessed whether NICE guidance was followed as part of the clinical audit programme to support and monitor the implementation of NICE guidance

Staff told us they had recently had an appraisal with their immediate line manager. However, some of the staff personnel files we reviewed showed that appraisal and performance reviews were inconsistent.

There was a programme to ensure that the surgeon was meeting his clinical supervisors every two weeks and reporting to the General Medical Council (GMC) every six months. Records showed feedback and review of cosmetic practice during the revalidation cycle. There was no evidence found at inspection, which would indicate that the surgeon was not complying with his GMC conditions.

Risk assessments were completed at each stage of the patient journey from admission to discharge; there was an escalation process if a patient deteriorated and clinical observations were recorded. The Early Warning Scoring System paperwork was on every case but it was only when there was a fluctuation in the observations and monitoring where the system was triggered. Following the inspection, the provider on completion of surgery started to identify that no early warning signs were noted.

There were processes for the control and prevention of infection. There were no surgical site infections. All areas were visibly clean.

Staffing levels were appropriate for the size of the service. Patient feedback was positive. The culture centred on the needs and experience of patients who used the service.

Are surgery services safe?

Incidents

- There was an incident reporting policy and the service used a paper-based reporting system to record incidents (an incident/accident book was held in the reception office). Staff told us incidents rarely occurred.
- Staff were not aware of any reported incidents and could not give us examples of lessons learned. The only incident staff could recall was several years ago which related to a needle stick injury.
- The aesthetic surgeon and manager said they tried to generate learning from incidents. Staff we spoke with were unaware of when to report an incident and were not clear on how to identify when an incident had occurred.
- We looked at a significant event analysis report, which occurred in 2016. The report contained details of the incident, action, and follow-up and risk assessment. The providers Medical Advisory Committee (MAC) discussed the incident. The membership was the provider, registered manager and an anaesthetist. There was an external cosmetic surgeon present, which provided independent scrutiny. However, the manager who had completed the incident investigation said they had not received training in Root Cause Analysis (RCA). RCA investigation is a well-recognised tool to ensure that lessons are learned to prevent the same incident occurring elsewhere.
- From November 2014, 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.
- Senior staff understood the principles of duty of candour although had limited experience in applying it in practice because of the very low number of incidents.
- There were no never events. These serious incidents are wholly preventable as guidance or safety recommendations that provider systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.

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

- The service unlike NHS trusts was not required to use the national safety thermometer to monitor areas such as venous thromboembolism (VTE) or pulmonary embolism (PE).
- The service did undertake patient risk assessments for VTE or PE as recommended by NICE clinical guideline CG92, and its recommendation for all healthcare professionals to follow the quality standard in the clinical guideline CG138.

Cleanliness, infection control and hygiene

- All of the areas we visited, including the theatre, preparation room and patient waiting areas were visibly clean.
- The operating theatre had air changes, was a sterile environment, and met national standards.
- Theatres were deep cleaned every month although we did not see any supporting documentation to corroborate this.
- Instruments and other equipment were cleaned using appropriate sterilising equipment. The decontamination of instruments was undertaken at the clinic using a steam steriliser, which was cleaned daily and serviced annually. Following each sterilisation cycle, the service retained documentation to evidence traceability.
- The manager told us they did not routinely screen patients for MRSA as there was minimal risk within cosmetic surgery. Patients were prescribed antibiotic prophylaxis.
- The service did not have a formal process for managing legionella in hot and cold water systems. The manager explained the water taps and toilets were regularly run and utilised throughout the day, as part of routine usage.
- The provider did not report any recent surgical site infections.
- There was access to personal protective equipment such as gloves and alcohol hand gel.
- At the time of inspection, most staff had completed infection prevention and control training in areas such as hand hygiene and disinfection and decontamination.

Environment and equipment

- The manager told us equipment was checked weekly but we did not see any documentation to support this. The manager showed us a book, which they planned to start using to document equipment checks.
- Individual companies maintained equipment, and relevant information was retained in a file in the management office. If any items were faulty, the service returned the equipment to the relevant manufacturer who would then send a replacement.
- The resuscitation trolley included appropriate equipment. The manager told us this was checked each week however; we did not see any documentation to corroborate this. The manager showed us a book and explained the service would use this to document all future checks.
- There were safe procedures for managing waste. Clinical waste was collected in appropriate waste bags and stored in a locked clinical waste bin, prior to collection. The same procedure applied for sharps bins.
- Flammable and hazardous substances, as defined by the Control of Substances Hazardous to Health Regulations (COSHH) guidelines, were appropriately stored in a locked cupboard. Within the cupboard, flammable substances were securely stored in a locked, metal box.
- Patients had access to a waiting room, prior to surgery, which they could use as a changing facility pre and post operatively.

Medicines

- The clinic had two drug fridges. We inspected the fridge in the preparation room and noted it was unlocked.
- Drug fridge temperatures were maintained between 2-8 degrees. The temperature was recorded. The fridge had an alarm operation system, which identified any deviance from 8 degrees, the maximum required temperature.
- Medication was stored in the preparation room in unlocked cupboards, one of which did not have a cupboard door.
- Controlled drugs were stored in a lockable cabinet and the (non-clinical) assistant manager retained the keys. According to medicines management guidelines produced by Nursing and Midwifery Council (NMC), a registered nurse or other appropriate practitioner should maintain responsibility for the keys. Out of hours, the key was locked in a lockable cabinet.

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- The manager told us they completed an audit of controlled drugs every month however we did not see documented evidence of this.
- We saw evidence of appropriate record keeping of controlled drugs. The documentation included the patient's name, date of birth, the type of drug used, and the provision of vials. However, we noted when part of a vial was given to a patient, the amount given and the amount wasted was not documented. This meant the service did not follow NMC standards for medicine management guidance.
- The service used a book to document and record all antibiotic medication provided to each patient. This included the dosage.
- Oxygen supplies were checked annually and the provider retained service reports.

Records

- Records were stored on a carousel within the management office. Although this room was unlocked during the day, the manager told us staff never left the office unattended at any time.
- The clinician completed a face-to-face comprehensive pre-assessment with every patient prior to surgery. This included all previous medical history including any existing health conditions. All medication and allergies were recorded. The provider wrote to the patient's GP seeking further relevant health information.
- Comprehensive notes about the surgical procedure were documented on the back of the consent form. This included details of the procedure undertaken, sutures, dressing, and medication.
- We reviewed the theatre register, which included information about every patient who had undergone a surgical procedure. Using a dedicated book, staff documented all appropriate personal and surgical information, including suture material if applicable.
- The service surgical implant book contained the patient's personal information, the type of procedure undertaken and a traceability sticker.

Safeguarding

- Staff had received safeguarding children and adults' training to Level 2 and the aesthetic surgeon was trained to level 3 safeguarding.
- Staff could explain what they would do if they had concerns about an adult or a child and gave examples of when they might make a referral.
- The service had a safeguarding adult's policy and referred to the national 'Working Together to Safeguard Children' guidance in relation to children and young people. The policy included information about who to contact if staff needed to raise an alert with the local authority. Patients travelled from all over the country to attend clinic however, the policy stated staff should only contact the local social services in Newcastle instead of the one where the patient lived.

Mandatory training

- Staff told us they accessed an online e-learning system to complete the majority of mandatory training although some training sessions were delivered in person, such as fire safety and CPR.
- We reviewed staff files, which showed the majority of training such as hand hygiene and safeguarding, were in date however, the records showed that fire awareness was completed in 2015. Cardio pulmonary defibrillation, chocking and anaphylaxis training was completed on 12 May 2017 by all staff. The surgeon and registered nurse were booked on ILS Training (Intermediate Life Support for intra-operative support) on 23rd August 2017
- Although staff had received training, information about training requirements and compliance was stored in individual personnel files. Managers did not have overall or immediate oversight of who had completed what training and when it was next due.

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

- Patient observations were monitored during and after surgery. The Early Warning Scoring System paperwork was on every case but it was only when there was a fluctuation in the observations that the system was triggered. Following the inspection, the provider started to document when early warning scores were within normal range.
- Staff completed the Safer Surgery Checklist, using the World Health Organisation documentation. Swabs and equipment were counted verbally between the operating surgeon and scrub nurse prior to and after surgery, however at the time of inspection the counts were not documented formally. The provider has since the inspection ensured that the counts are written formally and are confirmed on completion.
- In the event of a patient becoming acutely unwell before, during, or after a procedure, staff told us their

immediate course of action would be to administer emergency first aid and then call 999, if appropriate. The clinic had transfer arrangements with local acute hospitals.
- If a patient required sedation, the manager said the anaesthetist remained on site with the patient until they were safe to be discharged.
- Patients out of hours were advised to stay in local hotels. There were procedures to re-open theatre out of hours if any complications arose. Patients had access to call the surgeon 24 hours 7 days a week. The clinic provided all post-operative follow-up and care.
- Due to the nature of the treatment offered at the clinic, procedures were usually less than three hours.
- Surgical procedures carried out on-site were performed under local anaesthetic or conscious sedation. Records showed sedation followed a standardized administration protocol.

Nursing and support staffing

- There was one registered nurse, who supported clinical procedures in the capacity as a scrub nurse. An agency scrub nurse attended when there was a surgical procedure.
- We reviewed personnel files for all staff, which showed 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).

Medical staffing

- One aesthetic surgeon performed all clinical procedures. A consultant anaesthetist provided appropriate support when required. If they were unavailable on a day surgery had been booked, the manager told us they would cancel the planned procedure and arrange an alternative date.
- There were processes to ensure the anaesthetist was available to attend if a patient was readmitted to theatre in an emergency. There was an agreement with neighbouring NHS hospitals to provide anaesthetic cover if required.

Emergency awareness and training

- There were business continuity plans in the event of a major incident or disruption to services. There was a back-up facility to maintain power in the theatre, staff would subsequently shut down and cancel surgery with immediate effect.

Are surgery services effective?

Evidence-based care and treatment

- All of the policies we reviewed were in date and were accessible to staff in both paper and electronic versions. The assistant manager was responsible for reviewing and updating the policies, including all of the clinical policies. The service directors approved policies.
- The policies were based on relevant evidence-based guidance, best practice, and legislation, including the National Institute of Health and Care Excellence (NICE) and other professional bodies. However, it was not clear how the service assessed whether NICE guidance was followed as part of the clinical audit programme to support and monitor the implementation of NICE guidance.
- There was limited audit activity. Records showed that the assistant manager completed a surgical records audit every three months, which incorporated the WHO Surgical Safety Checklist. We reviewed the audit report and data showed the checklist was completed most of the time. The audit did not include any evidence of learning.
- There was a process to ensure that cosmetic pre-operative assessment included appropriate and relevant psychiatric history and discussion with patients about body image before surgery was carried out in line with Royal College of Surgeons guidance.
- The service was included in the Breast and Cosmetic Implant Registry. The registry is designed to record the details of any patient, who has breast implant surgery for any reason, so that they can be traced in the event of a product recall or other safety concern relating to a specific type of implant

Pain relief

- Prescribed local and conscious sedation medication was administered for effective pain relief during the procedure using a standardised administration protocol. Records we looked at showed this was followed correctly.

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Nutrition and hydration

- Patient survey results included comments about the provision of food and drink. Patients spoke positively about the refreshments and food they were offered during their visit.
- Fasting prior to surgery followed the sedation protocol. Patients who had surgery in the morning were asked to fast from 9pm the previous evening, for patients having surgery in the afternoon they were able to have a small breakfast. The usual fasting period was six hours prior to surgery.

Patient outcomes

- The surgeon had carried out 127 surgical procedures in the last 12 months. There were no unplanned transfers to theatre. In the last 12 months there was one revision for blepharoplasty
- The provider's statement of purpose said that the surgeon had performed over 2,600 aesthetic surgical procedures such as liposuction, breast augmentation, face and neck lift, brow lift, abdominoplasty and hair transplant. The revision rate had been 2-3% over a 17-year period. The surgeon said that this was done to improve the cosmetic appearance to help the patient achieve their goals, rather than complication management.
- The provider did not participate in the Royal College of Surgeons 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.
- At the time of our inspection, the provider had 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).

Competent staff

- There was an employee handbook, which managers confirmed was the basis for the induction of new staff joining the service. We spoke with a member of administrative staff who had recently joined the team. They told us they felt supported and were given the information and guidance to help them understand their new role. The agency theatre nurse had not received a local induction.
- Staff told us they had recently had an appraisal with their immediate line manager. However, some of the staff personnel files we reviewed showed that appraisal and performance reviews were inconsistent. For example, the records showed that the manager had received an external appraisal in June 2011, January 2013, and April 2017, the personal assistant had received an appraisal in January 2013 and May 2015, and the assistant manager had received an appraisal in June 2011, January 2013, and April 2017.
- The aesthetic surgeon had an appraisal by his supervisors on 21 May 2017, which was specific for the scope of practice. He had extensive continuing professional development during the year and was now a Fellow of the American Board of Aesthetic Surgeons. The surgeon confirmed that he had attended conferences relevant to liposuction, facelifts, and other cosmetic procedures.
- Letters showed that the surgeon was meeting his clinical supervisors every two weeks and reporting to the General Medical Council (GMC) every six months. Records showed feedback and review of cosmetic practice during the revalidation cycle.
- There was no evidence found at inspection, which would indicate that the surgeon was not complying with his GMC conditions.
- There were processes to ensure that the anaesthetist working at the clinic had the relevant skills and expertise for the procedures being undertaken. Records showed an appraisal was completed in January 2017, and practicing privileges reviewed in September 2016. Appropriate indemnity insurance was in place up to May 2018.

Multidisciplinary working

- Staff worked together to assess and plan on-going care and treatment. Because the team was small, communication was good and staff said they were able to deliver services in a co-ordinated way.
- The clinic worked with neighbouring trusts if a patient required emergency transfer or an overnight stay. There was access to the surgeon or anaesthetist 24 hours 7 days a week.

- There was agreement with a local NHS trust for pathology services, for example biopsy for excision of skin lesions.

Access to information

- Staff were able to access policies and procedures. Guidelines were in date and referenced relevant and current evidence based practice, standards, and legislation.
- There was evidence in the clinical records of correspondence between the service and the patients GP. Details of the surgery and any implant used were sent to the patient and to their GP.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- We observed a consultation for a patient requesting liposuction. The aesthetic surgeon went through the medical screening questionnaire. The cooling off period and a second consultation was offered.
- The aesthetic surgeon declared that he was a GP and had trained an alternative route.
- The surgeon was open about intentions and realistic expectations about the surgery. The examination was appropriate. The surgeon talked about the pricing policy openly, gave the patient information about the risks and benefits and alternative options including not pursuing surgery.
- We looked at five sets of clinical records, which showed consent was recorded appropriately. There was evidence of at least a two week cooling off period between the patient agreeing to undergo cosmetic surgery and the surgery being performed. This was in line with the Royal College of Surgeons Professional Standards for Cosmetic Surgery 2016.

Are surgery services well-led?

Leadership / culture of service related to this core service

- There were two directors, which was the aesthetic surgeon, and the manager who led the service.
- Staff we spoke with were positive about the leadership describing good relationships amongst staff and it being a 'no blame' culture.
- We found that the culture was centred on the needs and experience of patients who used the service.

Vision and strategy for this core service

- The Statement of Purpose indicated that the provider was committed to delivering the highest standards of health care available to patients and it strived to maintain customer satisfaction, by tailoring treatment to the individual.

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

- There was a risk management policy; however, the systems to capture information about all categories of risk were informal. The processes did not provide assurance of effective arrangements to monitor and manage quality and performance and to identify the action taken to improve.
- The systematic programme of clinical and internal audit used to monitor quality and systems to identify where action should be taken were limited.
- The provider had a MAC, which met quarterly. Membership was the two directors and anaesthetist. The minutes of January and April 2017 showed areas discussed included incidents, complaints, and operational issues. The minutes were sent to the surgeon's supervisors. There was evidence of changes in practice following an incident. This included amendments to guidelines. It was not clear how learning and improvement was shared with staff.
- There was a process for the provider to act on any alerts for example from the Medicines and Healthcare Products Regulatory Agency. Alerts were reviewed and action taken if it was relevant to the service.
- The provider 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.
- Certificates showed that surgeons carrying out cosmetic surgery had the appropriate level of valid professional indemnity insurance.

Public and staff engagement

- The April 2017 patient feedback survey from 40 patients showed that responses about the service were the same or better when compared with similar benchmarked services. Patients said they were satisfied with their visit, had confidence in staff ability, and received reassurance.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure there are effective arrangements to capture information about all categories of risk to monitor and manage quality and performance and to identify the action taken to improve.
- Ensure a systematic programme of clinical, internal, and external audit to monitor quality and systems to identify where action should be taken.
- Ensure that a risk register is developed to capture the recording of identified risks, dates, actions, and outcomes.
- Ensure systems are in place for the safe storage, security, and recording of medicines.

Action the provider SHOULD take to improve

- Ensure that there is a formalised incident reporting process to ensure that all staff are aware of how to report an incident and identify when an incident has occurred.
- Ensure effective systems for the recording of equipment checks in line with professional guidance.
- Ensure effective recording systems to provide immediate managerial oversight of staff training requirements.
- Ensure effective systems to record staff appraisal.
- Review guidelines to ensure appropriate recording of swab and equipment checks post operatively.
- Review processes to assess whether NICE guidance is followed as part of the clinical audit programme to support and monitor the implementation of NICE guidance.

This section is primarily information for the provider

Requirement notices

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
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment 12 (1) Care and treatment must be provided in a safe way for service users; (2) (g) the safe management of medicines. **How the regulation was not being met:** The systems did not enable the safe storage, security and recording of medicines.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance 17 (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. 17 2 (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. **How the regulation was not being met:** The provider did not ensure systems or processes were established and operated effectively to ensure compliance with the regulation.

This section is primarily information for the provider

Requirement notices

The provider did not have formal systems in place that were of a sufficient quality to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.