The Clear Ear Clinic

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

Ratings

Overall rating for this location

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Summary of findings

Letter from the Chief Inspector of Hospitals

The Clear Ear Clinic is operated by Clear Ear Clinic Limited. The service has no inpatient beds. Facilities include two clinic rooms, with operating microscopes and low-pressure suction systems to remove ear wax.

The service provides appointments on an outpatient basis to patients. We inspected the service using appropriate key lines of enquiry from our framework for outpatients and diagnostic imaging.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 13 July 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.

Services we do not rate

We regulate clinics that provide treatment on an outpatient basis 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 areas of good practice:

- The environment throughout the clinic was visibly clean and tidy.
- Equipment was readily available and tested regularly to ensure it was suitable for use on patients.
- Stock medicines and prescription pads were managed and stored appropriately. Nursing staff had been supported to become nurse prescribers.
- There were sufficient nursing and medical staff. We observed good working relationships between all grades of staff and professional disciplines, with communication with GPs initiated where necessary.
- Staff had awareness of what actions they would take in the event of a major incident, such as a fire.
- The clinic was open six days a week, with evening and weekend lists to suit patient need. Patients were able to access care and treatment in a timely way.
- All staff received appraisals and were happy with the quality of these and their clinical professional development opportunities.
- We observed systems in place to obtain consent from patients before carrying out a procedure or providing treatment. Patients were given sufficient information and time to give informed consent to the microsuction procedure.
- Interactions between staff and patients were observed to be positive across the clinic, with the patient at the centre of the care. All patients we spoke to and feedback we gathered was complimentary about the staff and the clinic as a whole.
- The needs of individuals with differing complex needs were well considered and largely met by the service. A telephone translation service was available. Clinicians were sensitive to the potential emotional needs of patients.
- There were a low number of complaints. When complaints were received they were used to identify learning and improve patient experience.

Summary of findings

- The clinic had an overall vision and strategy and communicated this to staff, enabling them to feel involved in the development of the service.
- Nursing and medical staff thought that the registered manager was supportive and approachable. They felt able to raise concerns.
- Feedback was sought from staff and the public to develop and improve the service, as appropriate.

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

- Not all staff were fully aware of their responsibilities under the duty of candour regulation.
- Hand hygiene practices were variable, with staff not always washing their hands between patients, as per policy.
- An expired vial of adrenalin was found in the resuscitation bag. This was immediately highlighted to the registered manager, who removed it. We were shown evidence that it was replaced following inspection.
- Clinical staff were not trained in the appropriate level of safeguarding, although they could describe how to recognise and escalate concerns. The provider had already started to action this by training all registered nurses post-inspection.
- Some staff had not familiarised themselves with some clinical policies, and some had not been updated since October 2015.
- There was no formalised risk register, with risk assessment forms being used instead. Some risks identified during inspection did not have a corresponding risk assessment. Risks were not graded according to severity or likelihood of event.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with two requirement notices. Details are at the end of the report.

Professor Edward Baker
Chief Inspector of Hospitals

Summary of findings

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Background to The Clear Ear Clinic

The Clear Ear Clinic is operated by Clear Ear Clinic Limited. The service opened in 2006. It is a private clinic in London offering aural microsuction. Microsuction is a method of removing earwax, foreign bodies and treating ear infections of the external ear canal. The method enlists the use of an operating microscope and a low-pressure suction system. The clinic accepts self-referrals from patients living in London and internationally.

The clinic has had a registered manager, Mary Kelly, in post since 2013.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector and a specialist advisor with expertise in ear, nose and throat services (ENT). The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

Why we carried out this inspection

This was the clinic's first scheduled comprehensive inspection.

How we carried out this inspection

During the inspection, we visited the whole clinic. We spoke with five staff including: a registered nurse, reception staff, medical staff, a locum consultant and a senior manager. We spoke with seven patients and one relative. We also received 19 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed 12 sets of patient records.

Information about The Clear Ear Clinic

The clinic is registered to provide the following regulated activities:

- Treatment of disease, disorder or injury

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with CQC.

Activity (April 2016 to March 2017)

- In the reporting period April 2016 to March 2017, there were 9,912 day case episodes of care recorded at the service. Of these, 145 patients were children from the ages of four to 15 years and 11 patients were young adults aged 16-17 years All of these were privately funded.
- There were no overnight beds.

Two ENT consultants worked at the hospital under a locum agreement. There were two full-time registered nurses and two part-time receptionists, as well as a dedicated part-time bookkeeper.

Summary of this inspection

Track record on safety between April 2016 and March 2017:

- No never events
- No record of clinical incidents
- No record of serious injuries
- No incidences of hospital acquired MRSA, methicillin-sensitive Staphylococcus aureus (MSSA), Clostridium difficile (c.diff) or hospital acquired E-Coli.
- One complaint

Services accredited by a national body:

- Nil

Services provided at the hospital under service level agreement:

- Peninsula: Work health and Safety, Human Resources, Fire Safety -risk assessments
- Initial waste Management : medical waste
- BOC: Oxygen cylinder
- Zeiss: Microscopes and service agreements
- Eschmann: Autoclave and service agreements
- Cliniko: Patient data Software
- ICO: Information commission office
- PCI DSS: World pay security portal (Payment card industry data security standard compliance)
- Balens: Medical /Indemnity Insurance
- RSA: public liability and contents, terrorist and loss of income insurance
- iHasco: Continous Professional Development
- Pimlico Electricians: Portable appliance testing
- GBUK: Suction machines and service agreements
- Water Cooler Company: Water Cooler and service agreement
- OHEAP: Fire Extinguishers
- PHLINTH: Patient couches and services
- Herbie's Cleaning Service: Housekeeper
- White Rose: dry cleaners and laundry.
- John Bell and Croydon: Pharmacy
- Joelson Solicitors: Solicitors
- BT: Firewalls and dedicated secure telephone and internet lines.
- Stammers Services: window cleaning contractors
- Infection Prevention Solutions: IPC CPD
- Wigmore Medical Training: CPR and Anaphylaxis training course.
- CSM Archiving and Storage: Archiving and storage.
- ENT UK: pamphlets

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate clinics that provide treatment on an outpatient basis.

We found the following areas of good practice:

- The environment throughout the clinic was visibly clean and tidy.
- Equipment was readily available and tested regularly to ensure it was suitable for use on patients.
- Stock medicines and prescription pads were managed and stored appropriately. Nursing staff had been supported to become nurse prescribers.
- There were sufficient nursing and medical staff.
- Staff had awareness of what actions they would take in the event of a major incident, such as a fire.

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

- Not all staff were fully aware of their responsibilities under the duty of candour regulation.
- Clinical staff were not trained in the appropriate level of safeguarding training, although nursing staff demonstrated an awareness of how to recognise if someone was at risk or had been exposed to abuse. They knew how to escalate concerns. The provider had already started to action this by training all registered nurses post-inspection.
- Hand hygiene practices were variable, with staff not always washing their hands between patients, as per policy.
- An expired vial of adrenalin was found in the resuscitation bag. This was immediately removed and we were shown evidence that it was replaced following inspection.

Are services effective?

We do not currently have a legal duty to rate clinics that provide treatment on an outpatient basis.

We found the following areas of good practice:

- Water and cool drinks in warmer months were readily available for patients.
- The clinic was open six days a week, with evening and weekend lists to suit patient need.

Summary of this inspection

- We observed good working relationships between all grades of staff and professional disciplines, with communication with GPs initiated where necessary.
- All staff received appraisals and were happy with the quality of these and their clinical professional development opportunities.
- We observed systems in place to obtain consent from patients before carrying out a procedure or providing treatment.

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

- Some staff had not familiarised themselves with some clinical policies, and some had not been updated since October 2015.

Are services caring?

We do not currently have a legal duty to rate clinics that provide treatment on an outpatient basis.

We found the following areas of good practice:

- Interactions between staff and patients were observed to be positive across the clinic, with the patient at the centre of the care.
- All patients we spoke to and feedback we gathered was complimentary about the staff and the clinic as a whole.
- Patients were given sufficient information and time to give informed consent to the microsuction procedure.
- Clinicians were sensitive to the potential emotional needs of patients.

Are services responsive?

We do not currently have a legal duty to rate clinics that provide treatment on an outpatient basis.

We found the following areas of good practice:

- Patients were able to access care and treatment in a timely way, with a choice of appointment times to suit their needs.
- The needs of individuals with differing complex needs were well considered and largely met by the service.
- A telephone translation service was available.
- There were a low number of complaints. When complaints were received they were used to identify learning and improve patient experience.

Are services well-led?

We do not currently have a legal duty to rate clinics that provide treatment on an outpatient basis.

Summary of this inspection

We found the following areas of good practice:

- The clinic had an overall vision and strategy and communicated this to staff, enabling them to feel involved in the development of the service.
- Nursing and medical staff thought that the registered manager was supportive and approachable. They felt able to raise concerns.
- Feedback was sought from staff and the public to develop and improve the service, as appropriate.

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

- There was no formalised risk register, with written risk assessment forms being used instead. Some risks identified during inspection did not have a corresponding risk assessment. Risks were not graded according to severity or likelihood of event.

Outpatients and diagnostic imaging

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are outpatients and diagnostic imaging services safe?

Incidents

- There had been no never events at the clinic between April 2016 to March 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There had been no incidents, clinical or non-clinical, reported at the clinic between April 2016 and March 2017. Staff that we spoke to knew how to report an incident, using the accident book and risk assessment board. We were shown evidence that the last reported incident was in 2015. Although the clinic's policy stated that an incident was a slip, trip or fall or any injury at work, this incident involved a patient fall. All staff were aware of this incident and the mitigating action of placing socks on the feet of the examination tables as a result. Staff told us that any potential learning from incidents would be discussed in the monthly team meeting. Senior staff told us that any clinical incident occurring through a procedure would be reported in the same way. This was referenced in the main microsuction policy. We were provided with a copy of an incident report for expired medication that was found on inspection. This was recorded on the same type of form that we were shown that an identified risk was recorded on.
- The duty of candour (DoC) 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. This means providers must be open and honest with service users and other 'relevant persons' (people acting lawfully on behalf of service users) when things go wrong with care and treatment, giving them reasonable support, truthful information and a written apology. There were no incidents during the reporting time period that met the threshold for DoC. Not all staff were fully aware of their responsibilities under this regulatory duty, with staff able to explain the principles in a broad sense, but not that a verbal and written apology must be given to the patient.

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

- The clinic, unlike NHS trusts, was not required to use the national safety thermometer to monitor areas such as venous thromboembolism (VTE). The clinic did not use any clinical quality dashboards to monitor safety due to the nature and size of the service.

Cleanliness, infection control and hygiene

- All areas that we inspected were visibly clean, including equipment. There were 'no touch' bins available throughout the clinic to minimise infection risk. We observed the practitioners clean down the couch and portable equipment after each patient use. In addition, every morning and afternoon, the practitioners cleaned the room, with a checklist being completed at the start and end of each day. A cleaner also attended every evening, who the registered manager met with on a monthly basis to check in with and discuss any potential issues.
- All clinical staff had attended Royal College of Nursing (RCN) accredited infection prevention and control (IPC) training in June 2017. This was provided face-to-face by an external company, over the course of two days. There was an IPC manual available to staff with up-to-date copies of polices on topics such as surface

decontamination, management of infections and management of healthcare waste, amongst others. Several patient comment cards commented on how clean and hygienic the clinic was.

- Staff were aware of measures to take to limit the spread of infection. Medical and nursing staff described how they would use a different tube on each ear to ensure any ear infection did not spread to the other ear. Everything else apart from tubing was single-use for each ear. Senior staff told us that they had never had patients report an acquired infection from the clinic.
- All instruments that were not single-use were placed into used instrument containers in the clinical rooms. All instruments at the end of day were then manually washed in the dirty sink (clinical room) with anti-bacterial wash and rinsed thoroughly under running water. Once dry, these were then placed in autoclave-dated bags as per protocol. An autoclave is a pressure chamber that is used to sterilize equipment and supplies. The autoclave was checked on a daily basis by clinical staff and a record of this was seen on inspection.
- The clinic did not screen patients routinely for MRSA or other multiple drug resistant organisms as they had no inpatients, and it did not apply to the setting and types of procedures undertaken.
- Clinical waste disposal was provided through a service-level agreement (SLA) with an external provider. Waste was collected on a weekly basis directly from the clinical bins in the treatment rooms as they were never full. During the inspection, we observed waste being disposed of correctly by staff. Sharps containers were dated and signed when assembled, not overfilled and temporarily closed when not in use. These were collected every two weeks by the same external company.
- Adequate supplies of personal protective equipment (PPE) including gloves and aprons, were available, although practitioners explained that they did not use these in the normal course of their work as there was minimal patient contact and no contact with bodily fluids. We observed adherence to 'bare below elbows' (BBE) dress code throughout the inspection.
- There were dispensers with hand sanitising gel situated in appropriate places around the unit. Guidance for effective hand washing was displayed above hand washbasins. Hand washbasins were equipped with soap and disposable towels. The clinic conducted a monthly '5 moments' hand washing audit using the WHO observation format, which was showed 100% compliance between January and April 2017. However, we observed variable compliance with the clinic's own policy regarding hand hygiene, which stated, "Wash hands- prior and after each patient and as required." On observing the treatment of six patients, there were five occasions out of the twelve (before and after each patient) where a practitioner did not clean their hands.
- The service conducted a daily house keeping and cleaning audit, where manual cleaning, sterilising protocol, microscope cleaning, restocking, waste management, instrumentation and the environment of each area was checked. In the six month prior to the inspection, most areas scored 100%, with some minor problems with restocking handtowels in one week in January.

Environment and equipment

- All services, including reception, the waiting area and treatment rooms were located on the third floor of Lister House. There was step-free access to the service via a lift. The building had a manager and reception staff at the front door, who welcomed and directed all patients, as well as providing assistance to any people with mobility issues who required wheelchair access via portable ramps.
- Each treatment room was equipped with an ear, nose and throat (ENT) microscope, electronic patient couch and suction equipment. All portable equipment and microscopes we checked had been recently serviced and labelled to indicate the next review date. Details of all equipment and servicing was kept for staff to view in the health and safety manual. Disposable equipment was easily available, in date and appropriately stored.
- A full range of resuscitation equipment was readily available and checked monthly by staff. Emergency drugs were available and within the use by date, apart from one vial of adrenalin, which had expired in November 2016. This was raised with the registered manager, who provided us with evidence that this was returned to the pharmacy and replaced promptly

following inspection. The defibrillator was shared with the clinic downstairs, and although there was no formal record of this agreement at the time of inspection, one was arranged following this issue being raised.

Medicines

- There was a medicine management policy (due for review December 2017) in place.
- The clinic had a stock of antibiotic ear drops and softening drops. There was a stock prescription for this written by on a 'clinic use only script' by one of the locum doctors. Medications were checked weekly by nurse practitioners and the manager, with expiry dates, ordering dates and quantity recorded in the medication book. Stock medicines were only given as first dose to the patient, then prescribed by a clinician for the patient to collect at their choice of pharmacy. All stock medications checked were in date. Prescription pads were stored securely, locked away, when not in use.
- Nurses had been trained to prescribe medications to patients as registered nurse prescribers, within their competency and scope of practice, to enable them to prescribe ear drops or topical presentations to patients.
- Medicines were stored in a secure locked safe with access by a key stored in another locked box, with a combination known only to medical and nursing staff. The temperature of the medications was monitored with a room temperature device in the cupboard. All topical drops were stored under the recommended temperature of 25 degrees Celsius.
- No controlled drugs were in use or stored at the clinic.

Records

- Patient records were stored electronically. The clinic's microsuction notes were stored within their patient software, which also kept a record of which treatment room each patient was seen in. This was a web-based service so could also be accessed from other clinic devices, such as tablets or mobile phones. No patients had been seen without records in the year prior to inspection. In the event of a power failure, the provider informed us that notes would be written by hand and stored in cabinets, until they could be entered onto the system. All hand written records, including the paper referral form, were securely filed and then removed and stored in a dedicated archive and storage facility off site. No medical records were removed off site by staff members.
- All patients having microsuction at the clinic were required to fill out a card that asked about allergies and informed patients to ask if they would like a GP letter about their treatment. A further assessment was then filled in online by the clinician, who took a medical history, description of the problem and any need for consideration during the procedure, such as needing an interpreter or being unable to support a supine position. We looked at 12 patient records which all contained an assessment of the patient and post procedure advice, such as standard ear care and keeping the ears dry.

Safeguarding

- Staff demonstrated an awareness of safeguarding procedures and how to recognise if someone was at risk or had been exposed to abuse. Staff had access to the up-to-date safeguarding policy in the information folder, with flow charts for the escalation of concerns available. Safeguarding was part of the clinic's mandatory training, with data indicating that 100% of relevant clinical staff were compliant with level 2 safeguarding children and safeguarding vulnerable adults training. However, all clinical staff working with children should be trained to level 3, according to the intercollegiate safeguarding framework. The provider had already started to action this by training all registered nurses post-inspection.
- Between April 2016 and March 2017, the clinic did not report any safeguarding concerns to the local authority and no notifications were recorded by the CQC. However, the registered manager was clear on how she would do this and who else to inform if any concerns were raised by staff.

Mandatory training

- Mandatory training included: fire safety, safeguarding adults and children, general policies and procedures and data protection. All staff were required to read and sign a confirmation sheet that these had been completed. In addition, clinical staff had to complete cardiopulmonary resuscitation (CPR) and anaphylaxis training, an IPC course, a prescribing course and an ear microsuction course. There was specific training required to carry out microsuction, in the form of

in-service education and a competency assessment. We were shown records that indicated all staff had completed their mandatory training. Although locums completed training through the NHS or an external company, they also joined in clinic training where appropriate.

- There were reliable arrangements in place for supporting and managing new nurses, including a comprehensive induction and a supernumerary period, during which senior staff assessed their clinical competencies. One member of staff had been supported in her role for six months before feeling confident enough to perform procedures alone, and the registered manager had been fully supportive of this.

Assessing and responding to patient risk

- All four clinical staff had up-to-date training in CPR and anaphylaxis, in paediatrics, as well as adults. All staff were trained in basic life support (BLS), with locum consultants with training in advanced life support (ALS) through their NHS contracts. If there was a medical emergency at the clinic either during, or after, microsuction which required emergency care, the clinic used the 999 service to transfer the patient to the local emergency department. There was a written emergency medicine policy to reflect this, although no such event had occurred at the clinic.
- The clinic would not treat any patient with more than a simple ear infection. If a patient had any complications, we were assured by staff that the clinic would advise them to return to their GP to see a specialist. For example, if polyps or a benign tumour was found in the ear on examination, this would be explained to the patient and in a GP letter, to enable onwards referral.

Nursing and other staffing

- There were two whole time equivalent (WTE) registered nurses, in addition to the registered manager (who was also a registered nurse). All nurses were able to perform microsuction and write prescriptions, and so worked alongside the locum doctors in the two treatment rooms. There had been no use of bank or agency in the year prior to inspection, as the registered manager explained that they were a specialised clinic, with bank and agency nurses not possessing the required skill mix.
- Between April 2016 and March 2017, no registered nurses had been recorded as absent from work as sick. The registered manager was available to cover in the case of sickness absence.
- There had also been no turnover in this period, although we were told that one of the nursing staff was leaving on the Friday following inspection, due to work life balance reasons. Another member of staff had been recruited into this post, due to start in September. We were shown rotas that evidenced this would not impact on the running of the service. All nursing staff recruited to the clinic were expected to have at least two years of ENT experience.
- There were also two part-time receptionists, who worked 18 hours each. They had been encouraged to sit in on microsuction procedures so as to understand what the clinic did for patients.
- Rotas were worked out three months in advance, with staff able to request specific shifts and book annual leave on an online system. There were always at least two people working on a Saturday, even if only one practitioner was running a list, which complied with the clinic's lone working policy.

Medical staffing

- At the time of our inspection, there were two locum registrars employed through an external company. The clinic kept records of their GMC registration, revalidation and ENT training. They were also expected to complete mandatory training through their NHS trust, or through the external company and with the clinic, for certain topics.
- Medical staff worked alongside nursing staff in one of the two treatment rooms, providing their availability ahead of time to enable rotas to be drawn up. The locum doctors also provided the clinic with their availability when they were not in dedicated sessions, in case any sickness relief was required. Another locum was being interviewed in the week following inspection, due to the relatively quick changeover of medical staff as they progressed with their NHS training.

Emergency awareness and training

- Staff had awareness of what actions they would take in the event of a major incident, including a fire. Across the clinic, all staff had completed fire safety awareness

training this year. The last fire safety drill was held in January 2017, with another due. The clinic had recently changed doors and locks to comply with updated fire regulations. All fire extinguishers at the building were within their service dates.

Are outpatients and diagnostic imaging services effective?

Evidence-based care and treatment

- Policies and procedures were available in a folder at the clinic. Clinical policies and procedures we reviewed all referenced relevant national guidelines. All had been recently reviewed, or were due to be reviewed later this year. Not all staff had familiarised themselves with all policies recently, some not being signed or updated since October 2015. The registered manager informed us that this would be the clinic's first priority after the busy summer period, when fewer patients would be attending the clinic.
- The clinic performed limited local audits in line with their scope of practice, such as a monthly environmental audit that monitored waste disposal, hand washing and general cleaning. The service did not conduct audits in areas such as consent or medication.
- The clinic had no formal admission policy or criteria, although we were told by staff that only simple ear infections would be treated at the clinic. Any patients who lacked capacity to consent to treatment would also not be seen at the clinic. A standard policy document would ensure consistency.

Pain relief

- The service did not capture specific feedback on pain relief, although patients were asked if one of their presenting problems was ear pain (otalgia). There were no formal pain assessment tools used by the clinic, but a subjective grade was assessed in the history. The improvement of any symptoms would then be assessed verbally after the treatment was delivered.

Nutrition and hydration

- The clinic did not need to consider the nutrition of patients due to the short wait and appointment times. However, a water cooler was available in the main reception for patient use. The clinic also informed us that cooled drinks were supplied for patients in the warmer months, if necessary.

Patient outcomes

- The service was not associated with national audits as there were no long term results that required monitoring at the clinic. The service monitored patient outcomes through formal feedback, through their website and twice yearly patient survey. Over 65% of their service users came to the clinic through 'word of mouth' and internet searches, recommended either from friends or family members. The clinic had many returning customers, who preferred this method of wax removal to those offered by the NHS.
- The clinic had contacted the Private Health Information Network (PHIN) with a view to act in accordance with legal requirements regulated by the Competition and Marketing Authority, but had not received a response at the time of inspection.

Competent staff

- The clinic reported that all nursing and other staff had had an annual appraisal in the previous year. Staff we talked with confirmed this. Staff reported they were generally happy with the appraisal system and process, which allowed them to identify their continuing professional development (CPD) needs.
- Medical staff completed training through the NHS or an external company, they also joined in clinic training where appropriate. All doctors used in the clinic had supplied evidence of current revalidation.
- An external company provided opportunities for free e-learning, with new modules released each month. The manager of the clinic was happy to support her staff in additional training, as long as it had relevance to the clinic. An example of this was nursing staff being supported to become nurse prescribers, through a six month course alongside their work. Staff had also just signed up to a course to improve their computer skills.
- The two directors of the company ran a yearly two day course in ear microsuction with the Ear Institute at the Royal National Throat, Nose and Ear Hospital. They also gave lectures for British audiology association, with the next due in September 2017.

Outpatients and diagnostic imaging

Multidisciplinary working

- We observed good working relationships between all grades of staff and professional disciplines. Doctors and nurses were complimentary about the support they received from one another.
- All patients were made aware that the clinic could send communication to their GP, although this was not standard for routine microsuction procedures. If this was required, a discharge letter was generated and sent to the patient's GP, or given to the patient to take with them if they preferred. This was to ensure the GP was aware of the procedure and of any wider issues found, if needed. The discharge letters also included contact details for the clinic, should another health professional require further information.

Seven-day services

- The clinic was open six days a week. On Monday, Wednesday, Friday and Saturday, opening hours were 9am until 5pm. On Tuesdays and Thursdays, the clinic was open later until 7pm to offer flexibility to those who worked. Patients we spoke to praised the clinic for the availability of appointments, with one patient telling us that Saturday appointments were, "such a good convenience."

Access to information

- There were sufficient computers available in all areas of the clinic, which gave staff ready access to patient records and information.
- Paper copies of policies and procedures were kept in the clinic, with easy access for staff.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- There were systems in place to obtain consent from patients before carrying out a procedure or providing treatment, which we saw evidence of in patients' notes. All of the clinic's patients gave consent both in writing and verbally, as well as stating their allergies, before proceeding with treatment.
- We observed staff gaining informed consent from patients before giving care and treatment, including from a nine year old child. He was allocated a longer 30 minute appointment and both him and his father were involved in the consultation, with explanation given of the method, equipment used and sensations to expect. Informed consent was given by both parent and child before the procedure commenced. The provider did not train staff specifically in Gillick competency, but told us that clinicians were aware of this through their NHS work and medical training. The provider told us that their consent process was directed at each individual patient and delivered in manner compatible with their level of understanding. If the patient did not hold still during the procedure, the clinician could not do it. There was no way to physically perform the procedure in an unwilling patient, no matter their age or Gillick competence. The provider commented, "in that way any child has final say, no matter what the desires of the parent or what the law deems their comprehension to be."
- An up-to-date copy of the clinic's consent policy was available to staff, along with a copy of the Mental Capacity Act 2005 (MCA), in the information folder. We were told by senior staff that the due to the nature of the service and the necessity of self-referral, patients who lacked capacity were not treated at the clinic.

Are outpatients and diagnostic imaging services caring?

Compassionate care

- The clinic environment ensured privacy as patients were treated privately in each treatment room. Nurses and doctors introduced themselves to patients. Interactions between staff and patients were observed to be positive across the clinic. Staff treated patients with compassion and respect. We observed staff reassuring patients and answering questions about their care.
- The seven patients and one relative we spoke with all provided positive feedback about the treatment and care they received from the clinic staff. They said the staff were "very good", "reassuring" and "kind and knowledgeable." Patients felt listened to and able to ask questions. One patient told us happily, "I can hear again!" and that the customer care was excellent. Patients described the feeling of "relief" after the treatment and commented on the "ease" of the procedure, which was "much less traumatic" than syringing, once explained by the clinical practitioner.

Outpatients and diagnostic imaging

- The clinic collected twice yearly feedback from patients. The last survey of 100 participants, conducted in March 2017, found that 100% asked agreed that the reception staff were welcoming, friendly and informative. A further 99% of patients would recommend the procedure and clinic. The results of the October 2016 survey were broadly similar. There was a comment box available all year round to collect patient feedback continuously. Patients could also leave comments on the clinic's website.
- We received 19 patient comment cards in the weeks preceding inspection, all of which gave positive feedback about the clinic. This ranged from simply, 'happy ears again' to comments about the quality of the service, with staff who were 'professional', 'always polite and friendly' and 'caring and polite'.

Understanding and involvement of patients and those close to them

- The clinic produced a detailed brochure on microsuction treatment that provided costs of treatments for patients. The website also provided clear information about the cost of procedures. In the survey of 100 patients in March 2017, 99% of respondents felt 'extremely satisfied' regarding cost information. Patients were verbally reminded of treatment cost when making an appointment or an enquiry, as well as at the time of treatment. We saw that where there had been patient confusion about a free consultation, staff had been asked to clarify that patients would be assessed and then informed if a further treatment cost would be incurred.
- We saw a detailed information leaflet for patients and relatives explaining what to expect from the microsuction procedure. Patients told us that they were well informed by both the literature and the explanation given by the doctor or nurse, prior to treatment. We observed clinicians explaining the procedure and giving patients and relatives time to ask any questions. One patient told us that they had initially been nervous, "but felt ready to give it a go" when the nurse explained in detail how the procedure would be done.
- In the survey of 100 patients in March 2017, 99% of respondents were 'extremely satisfied' that they had understood all information given, with 100% satisfied that they had understood risk information. Comments that we received on cards praised the staff and their ability to 'put you at ease' as they 'share the knowledge'. Information on standard ear care was given to patients to take home with them following their appointment.

Emotional support

- Receptionists told us that some appointment slots were blocked out as 'unavailable', to give clinicians time with patients who required enhanced support or care. We were given the example of telling someone they have a benign tumour in their ear. Staff also told us about some older clients who visited and were very lonely. They described how visiting the clinic was a social outing for them, and how giving them time to talk, and helping them to clean and work out how to use their hearing aids correctly, was important.
- We were told of different approaches that staff took towards those with mild cognitive issues or children, who may not be able to communicate so easily. One example was given of a child who visited the clinic and had previously been diagnosed with attention deficit hyperactivity disorder (ADHD). With patience and gentle persuasion from his parents and the clinician, the child allowed one ear to be treated. On the next visit, he came with jelly beans to give staff and told them, "I can hear" and let the other ear be treated. Staff recognised how the isolation and distorted noises experienced by those with hearing loss could be frightening and impact their lives.

Are outpatients and diagnostic imaging services responsive?

Service planning and delivery to meet the needs of local people

- The service offered appointments at evenings and weekends to offer flexibility and suit the needs of patients.
- Between April 2016 to March 2017, the clinic saw 145 children from the ages of four to 15 years and 11 young adults aged 16-17 years. Most equipment was standardised, enabling both adults and children to be treated. However treatment was tailored where necessary, with smaller sizes of speculum used for children, for example. Longer appointment times were

given to children as standard. The waiting room had children's books but no toys or materials for children to play with whilst waiting for a procedure. The provider told us that this was not necessary as children never waited long and usually brought their own electronic devices to play with.

Access and flow

- Patients could contact the clinic directly via email or telephone. The clinic receptionist would then book a patient into a clinic slot, based on their preference. Different colours were used to signify different appointment types and lengths on the electronic booking system (for example, new patient, for review or child), for easy reference.
- Patients we spoke with told us they were offered a choice of appointment times according to their need and availability. All were happy with the ease of booking an appointment and how quickly they were able to be seen. There were no wait times for appointments, with patients being seen on the same day if required. The clinic had capacity for up to 70 appointments per day across the two treatment rooms. There was a third treatment room they had considered opening up, but this was not necessary at this time as capacity was not stretched.
- Between April 2016 and March 2017, there were no cancelled appointments due to the clinic. A member of staff told us that there had previously been a small issue with some appointment lists running late due to patients not coming in on time. Patients had been informed that if they were more than 15 minutes late, their appointment would have to be rescheduled. This had improved timings of appointments. Patients were always informed if there was going to be a delay to their appointment.
- Patients were provided with general discharge information, which included instructions on standard ear care and the phone number of the clinic. No specific follow-up was given, unless the patient needed a review, in which case this was booked in before the patient left the clinic after first appointment.

Meeting people's individual needs

- The clinic's waiting area was clean and comfortable, with adequate seating. There was a water cooler and magazines available for those waiting.
- The clinic was accessible to those in wheelchairs, as they had purchased a wheelchair to fit in the small lift and were able to transfer patients, taking their usual wheelchair up the stairs. The long arm of the microscope meant it could be adjusted for patients in wheelchairs or those unable to lay supine. Any access needs were assessed on booking. The registered manager told us that they also had a portable suction unit and other magnification equipment that they could take downstairs if a patient was unable to come up, enabling some degree of relief of a patient's symptoms. We saw that this had been risk assessed and planned by the clinic.
- The survey of 100 patients in March 2017 found that 85% of patients were asked about whether they had any special needs on booking their appointment. We were told by clinical staff that where survey results were less than 95%, outcomes were improved through raising staff awareness, supporting staff in e-learning activities, staff development meetings and creating policy as an assistance tool for reference. In this instance, reception staff were reminded of the importance of providing holistic information and the electronic software was going to be updated to make this field mandatory to complete.
- The clinic had access to interpreters through the telephone provider, but found that patients often brought friends and relatives to translate for them, if necessary. Whilst not appropriate in a hospital setting, the minor nature of the treatment offered at the clinic did not make this particularly problematic.
- Staff described other ways of communicating with patients with communication barriers, such as using a pen and paper, or online translation tools, or a computer to make text bigger. Another blind and deaf patient had visited with a tablet and an application ('app') that he used to communicate on there, which staff were able to utilise. Two patients with learning difficulties also regularly attended the clinic with their parent or carer. Staff were able to describe how they would anticipate and cater for their needs.

- The clinic had information leaflets available for the procedure and for standard ear care management, as well as common ear conditions. Although information was patient friendly, these were only available in English.
- The service did not treat patients with severe cognitive impairments or dementia, but said that it could signpost families to other agencies that could help. Staff did talk about treating patients with Parkinson's or neuralgia, and how their tics were rhythmic and usually fit a pattern, enabling a clinician to complete the microsuction procedure safely.

Learning from complaints and concerns

- Information on how to make a complaint was available to patients. Patients were advised to make any verbal complaints to a member of staff, who escalated these to the registered manager as appropriate. Staff told us that the service would aim to resolve the complaint informally immediately, usually within four hours of an issue being raised, with the service user being contacted via phone or email to follow up, dependent on preference.
- Formal complaints were by handled by the registered manager, as per the up-to-date complaints policy. Patients were advised to put their complaint in writing, giving as much detail as possible. The service aimed to acknowledge complaints within two working days. The manager then carried out a full investigation into the complaint and agree on a solution. The clinic aimed to achieve a satisfactory outcome within five days.
- Between April 2016 and March 2017, there had been one formal complaint to the clinic. This involved a patient who was unable to access the clinic due to the lack of a wheelchair ramp on that day. As a result, the booking software was adjusted to flag patients with access arrangement and a discussion was held with ground floor staff about the importance of communication and having ramp availability. This complaint was resolved within the target timeframes. No complaints were referred to the Independent Healthcare Sector Complaints Adjudication Service (ISCAS).
- Learning and action points from any complaints were discussed in team meetings. We saw minuted evidence of a discussion of an informal complaint about a patient being unhappy about payment, which was discussed and an action plan shared, during a team meeting.

Are outpatients and diagnostic imaging services well-led?

Leadership and culture of service

- The leadership included two company directors, one of which was the registered manager. The registered manager was actively involved in the day-to-day running of the company, where she was on site and able to assist staff at all levels. Staff described her as "helpful" and "supportive", finding her easy to talk to, and ready to listen.
- The provider ensured that it was meeting Regulation 5: Fit and proper persons. We saw the provider had considered this regulation and that the registered manager met requirements, including providing evidence of a Disclosure and Barring Service (DBS) check.
- All staff we spoke with reported that they enjoyed working at the clinic and that members of staff were "just like a family". Good team work and morale was observed during the inspection, with staff telling us that they felt motivated, both through patient feedback and support from their colleagues.
- Staff told us that they felt confident to raise any concerns with the manager or the doctors. The registered manager stressed that she tried to keep an open culture at the clinic. We observed information leaflets on the unit encouraging staff to speak up (whistle blow) if they saw something was wrong. There was an up-to-date whistleblowing policy, which outlined how to escalate any concerns.

Vision and strategy for this this core service

- The clinic's vision was to provide safe, accessible and affordable ear care for patients with integrity and genuine customer care. Their strategy going forward was to develop this throughout the whole of the UK, with clinics modelled on the original service design. To this end, there was another planned clinic opening in

Oxford, towards the end of the 2017. Research into the demographics of their existing client base had found that over 60% of the clinic's current patients were from this region. There were plans in place to target local GP and health centres in the Oxford area to raise consumer awareness of the service. The service saw this as a trial to see how rolling out the model went and to see whether satellite clinics were the way forward. Staff at the clinic were aware and involved in the vision and strategy, with one of the nursing staff being added as an additional registered manager at the London clinic until the new location was established.

Governance, risk management and quality measurement

- There was a formal monthly meeting where topics pertinent to the running of the clinic, such as complaints, incidents, infection control, equipment testing, mandatory training updates, audit results and patient feedback were discussed as a team. There were also daily informal meetings where issues could be discussed in between meetings.
- There were individual risk assessments on topics such as cleaning (domestic and clinical), decontamination of medical devices, single use instrumentation and medication stock. The registered manager told us that any member of staff could send informal risk assessments to be discussed and formalised if deemed appropriate. Whilst on inspection, some risks such as those of a patient moving during a procedure, were identified by staff, but no risk assessment had been completed. There was a section in the microsuction policy that stated that a patient who cannot refrain from moving would be referred to their GP for booked into another appointment. However, this did not take into the account of accidental movement. Risks were not graded according to severity or likelihood of event.

Public and staff engagement

- Staff told us that there were regular staff meetings for all staff at the clinic, where all staff were encouraged to contribute. We reviewed minutes from these meetings and saw that all staff were involved in discussions.
- The clinic did not carry out any staff surveys as it was a small team. From speaking with staff, we found that staff at all levels were able to provide direct feedback and input into the running of the service, if they felt anything could be improved. Staff told us that they felt valued and like their views were listened to.
- Twice a year, patients and relatives were asked to complete a feedback questionnaire about their experience. Patients were also able to provide feedback via comments cards, the clinic website and direct email. We saw evidence that this feedback was collated and used to improve the service for patients.

Innovation, improvement and sustainability

- The service had discussed creating a 'development group' to enhance patient information and counselling, and to focus on primary prevention, contraindicated intervention, referral and coordination of care. The aims in developing the group and awareness would involve developing 'curriculums of learning' in ear care and management for general health care professionals. The clinic had approached both ENT UK and the General Medical Services (GMS) with their curriculum for consultation but had not yet received a reply. Once a response had been received, the clinic planned to negotiate a timeline with ENT UK and GMS.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that all clinical staff are trained in safeguarding children up to level 3, as per the intercollegiate guidance.
- The provider must ensure that all clinicians wash their hands before and after patient contact, as per policy.

Action the provider SHOULD take to improve

- The provider should ensure that all staff are familiar with their responsibilities under the duty of candour regulation.
- The provider should ensure that there is an effective system in place to check the expiry dates of emergency medication.
- The provider should ensure that all policies are reviewed and that staff familiarise themselves with these.
- The provider should consider the use of a formalised risk register, where risks are graded according to severity and likelihood of event. All risks identified during inspection should be added to this.

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 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The regulation was breached as clinical staff had only received safeguarding children level 2 training. However, all clinical staff working with children should be trained to level 3, according to the intercollegiate safeguarding framework.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • Assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated. Regulation 12 (h). The regulation was breached as clinical staff did not always wash their hands between patients, as per the clinic's own policy.