Thames Allergy Centre Ltd

Airedale Allergy Centre

Inspection report

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Overall summary

We carried out an unannounced responsive inspection at Airedale Allergy Clinic on 12 March 2018, following concerns which were raised with the Care Quality Commission. During the March 2018 inspection a breach of the regulations was identified in relation to the management of medicines, equipment and assessing and responding to patient risk. A warning notice was issued and the provider was told to improve.

This inspection was an announced comprehensive inspection carried out on 16 October 2018 to check that the clinic had responded to the warning notice dated 20 March 2018 and had made the required improvements.

The responsive report for the March 2018 inspection can be found by selecting the 'all reports' link for Airedale Allergy Clinic on our website at www.cqc.org.uk.

During this comprehensive follow up inspection on 16 October 2018 we asked the service the following key questions; Are services safe, effective, caring, responsive and well-led?

Our findings were:

Are services safe?

We found that this service was not providing safe care in accordance with the relevant regulations.

Are services effective?

We found that this service was not providing effective care in accordance with the relevant regulations.

Are services caring?

We found that this service was not providing caring services in accordance with the relevant regulations.

Are services responsive?

We found that this service was not providing responsive care in accordance with the relevant regulations.

Are services well-led?

We found that this service was not providing well-led care in accordance with the relevant regulations.

We carried out this inspection under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service had carried out the improvements required to comply with the warning notice dated 20 March 2018. Airedale Allergy Centre had failed to comply with Regulation 12 (1) Safe care and Treatment of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

At the March 2018 inspection, a number of concerns had been identified with regards to the safe management of medicines. This included compliance with Human Medicines Regulations (2012) and Nursing and Midwifery Council guidance. There were omissions in relation to the

Summary of findings

storage, labelling, manufacturing and administration arrangements for vaccines and infusions provided to patients. We were not assured all patients were appropriately assessed prior to receiving treatment. In addition, processes for gaining consent from patients did not follow best practice guidance. Staff training and competence showed a number of gaps and we were not assured that staff skills and knowledge were up to date. At the March 2018 inspection we had also identified a number of sterile items which had passed their expiry date; and electronic equipment testing had not taken place since 2013. Hand wash facilities were not available in the consulting or treatment room; although alcohol gel was available.

Airedale Allergy Centre is operated by Thames Allergy Centre Limited. The service investigates and aims to identify dietary, environmental or nutritional factors related to health problems. It also offers advice and treatment, including dietary modification and desensitisation. The service also manufactures, supplies and administers vaccines and intravenous infusions to patients.

At the time of our inspection this service was registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some general exemptions from regulation by CQC which relate to particular types of service and these are set out in Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. At Airedale Allergy Centre, services are provided to patients regardless of where they live. Patients who are seen in the clinic, but do not reside in England are out of CQC scope of registration.

At the time of our inspection the clinic was registered with the CQC for the regulated activity of Treatment of Disease, Disorder or Injury only. During our inspection it was highlighted that the clinic was also undertaking the regulated activity of Diagnostic and Screening Services. The provider is registered for the provision of this regulated activity, but not as a condition of registration from Airedale Allergy Centre.

The clinic administrator is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

During the inspection feedback was obtained through completed CQC comment cards and by speaking with one patient on the day. We received four comment cards on the day of inspection, and were shown one email sent by a patient. Seven patients contacted CQC through the 'share your experience' form on the CQC website, prior to the inspection. The majority of feedback from patients was positive. Patients told us they were treated with dignity and respect and that the staff were caring and listened to their concerns. Patients said they felt involved in decisions about their treatment. One patient told us that they had used two different clinics run by the provider, the patient stated there were inconsistencies in the information given and that they were unsure if the doses of medicines they were receiving were correct.

During our inspection on 16 October 2018, we identified a number of significant concerns which posed a serious risk to the life, health or wellbeing of patients at Airedale Allergy Centre. On the 19 October 2018, the Care Quality Commission applied to the Magistrates Court for an urgent cancellation of the registration of the service provider and the registered manager at Airedale Allergy Centre under section 30 of the Health and Social Care Act 2008.

The order was granted on 19 October 2018 and the registration of Thames Allergy Centre, in respect of the regulated activity of Treatment of disease, disorder or injury and that of the registered manager were cancelled at the Airedale Allergy Centre location with immediate effect. The provider was allowed 28 days to make an appeal against this decision. The provider appealed the decision to the First Tier Tribunal. The tribunal dismissed the appeal, therefore this service remains closed and is no longer registered with the Care Quality Commission.

Our key findings were:

- At this inspection we found that the provider had failed to respond appropriately to the warning notice issued on 20 March 2018. The provider had failed to

Summary of findings

ensure that under Regulation 12(1) of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; Safe Care and Treatment, was provided in a safe way for service users.

- There were serious deficiencies in the manufacturing, safe storage, quality control and record keeping arrangements for medicines.
- The provider failed to comply with legal requirements for the management of controlled drugs because they did not have appropriate record-keeping and safe custody arrangements in place. We saw that Morphine and Fentanyl which are both controlled drugs in Schedule 2 of the Misuse of Drugs Act 2001, were stored on the premises.
- During the inspection we found stock solutions used to prepare vaccines which had been produced up to 22 years ago. There was no scientific justification available to confirm the stability and sterility of these solutions or to confirm the effectiveness of the preservative used.
- The provider had failed to act on the advice of the Medicines and Healthcare Products Regulatory Agency (MHRA) regarding safety concerns with their manufacturing processes.
- The provider had failed to acquire a Manufacturer's 'Specials' Licence to carry out manufacturing activities as required by the MHRA.
- The clinic confirmed that a concentrated potassium chloride injection was used to make up intravenous infusions and had been administered to at least one patient. This medicine was the subject of a national patient safety alert issued in 2002 and can be fatal if administered inappropriately.
- The clinic offered face to face consultations for adults and children. In addition, telephone and Skype consultations were available for adults, and Skype consultations for children of any age. The clinic director told us there were no systems in place to confirm the identity of patients during remote consultations; nor were there systems to confirm parental identity or responsibility when consulting with children. They told us these issues had not been considered.
- The clinic did not respond appropriately to concerns raised by other health professionals or assess the capacity of patients when concerns were evident.
- The systems in place to manage infection prevention and control at the clinic were inappropriate and ineffective.
- The provider had not given due regard to the health and safety of patients using the clinic; including in respect of fire safety, the calibration of medical equipment, legionella checks, electrical safety and emergency procedures.
- Staff training did not follow the clinic's own policy, and gaps were identified.
- Recruitment procedures at the clinic did not keep people safe.
- The provider did not undertake any quality improvement activity.
- The provider and the registered manager demonstrated a lack of insight and oversight as to the requirements of managing the work to be performed.

Professor Steve Field CBE FRCP FFPH FRCGPChief Inspector of General Practice

Airedale Allergy Centre

Detailed findings

Background to this inspection

Airedale Allergy Centre is operated by Thames Allergy Centre Limited. The service has been operating since the early 1980's and Airedale Allergy Centre registered with the Care Quality Commission in 2013. It is an independent clinic located at 41 Devonshire Street, Keighley,

BD21 2BH, West Yorkshire. Referrals are also taken from outside this area. The service has had a registered manager in post since 2013 and this manager was in post at the time of our inspection.

The service investigates and aims to identify dietary, environmental or nutritional factors related to health problems. It also offers advice and treatment, including dietary modification and desensitisation. The service also manufactures, supplies and administers vaccines and intravenous infusions to patients. The majority of patients who are seen in the clinic pay privately for this service and the consultation fees are advertised on the clinics' website.

The clinic is open four days per week Monday, Tuesday, Thursday and Friday. Doctors do not attend the service on Mondays and Tuesdays when a nurse is available.

Our inspection team was led by a CQC lead inspector and included a second CQC inspector, a pharmacist specialist and a GP specialist advisor.

Prior to the inspection the provider completed an information request form to assist with our inspection planning.

We informed our stakeholders including Healthwatch and the local Clinical Commissioning Group that we were inspecting this service; however, we did not receive any information of concern from them. Airedale Allergy Centre is not commissioned by the local CCG.

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

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

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

Are services safe?

Our findings

We found that this service was not providing safe care in accordance with the relevant regulations. The inspection highlighted serious deficiencies in the quality of care provided which posed a significant risk to the life, health or wellbeing of patients.

We found the systems in place for managing medicines did not keep patients safe. Additionally, significant concerns were found in relation to the health and safety of patients and the management of infection, prevention and control. We did not see that safe recruitment procedures were in place or that the provider had considered the importance of safeguarding the welfare of children at the clinic.

Safety systems and processes

The service did not have systems to keep people safe and safeguarded from abuse.

- The service did not have appropriate systems in place to safeguard children and vulnerable adults from abuse. The provider did not follow their own policy in regard to safeguarding training. Staff training records evidenced that none of the clinical members of staff were up to date with child safeguarding training. One nurse had not attended any child safeguarding training since 2012, one doctor had attended training in 2016 but no further updates were evidenced. Contrary to their policy, the medical director did not have any documented training or certificates for child or adult safeguarding, fire safety, first aid or infection prevention and control and was not aware of recent updates to the safeguarding policy. The clinic did not have any record of the training or competencies of the locum nurse who worked at the practice every week.
- We were not assured that staff knew how to identify and report safeguarding concerns.
- The Registered Manager (RM) acted as a chaperone when required. We were told that they had received training in a previous role prior to 2013, we were not shown evidence of this.
- The RM confirmed that a doctor was not always present on the premises to support the nurse who was making vaccines and solutions including intravenous therapies, to administer and send away with patients. Nursing and Midwifery Council Standards for medicines management guidance states that wherever possible, two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the intravenous (IV) medication. We were told the second person who checked the IV infusion was 'often' the RM, who was not medically trained.
- During the inspection two medicines which had been brought in by patients were viewed on a shelf within the vaccine preparation room. The medicines had expired in 2013 and 2016. These medicines were accessible to patients, as was a further medicine we viewed which had expired in 2014 and also required refrigeration. Additionally, a number of sterile items within the clinic had expired. These included three boxes of syringes, a butterfly needle used to extract bloods and a spill kit. We also viewed a visibly dirty, used, auroscope cover (an auroscope is an instrument for looking in a patients' ears) in a consultation room. Bottles of solutions were visibly dirty and we saw there were labels which were tainted with mould.

Risks to patients

Systems were not in place to assess, monitor or manage risks to patient safety.

- The provider had conducted a health and safety risk assessment. They had safety policies in place. However, we saw numerous examples of where the provider had failed to follow their own policies including medicines management, safeguarding, fire and infection prevention and control (IPC). We were not assured that these policies were communicated to staff or that staff received safety information from the service as part of their induction or refresher training.
- The system to manage IPC was ineffective and had not been fully implemented or actioned. We were told that an audit had not been conducted.
- The clinic could not evidence that appropriate IPC measures were in place in line with legislation. Each of the five refrigerators used to store solutions and vaccines were consistently noted to be out of range and therefore ineffective. Refrigerator '5' was noted to be out of range on 80 occasions over 51 days from 11 June 2018 onwards. Cleaning schedules completed by the nurse for the three consultation rooms were

sporadically completed by a 'tick' only, no detail of what was cleaned was available and documents showed that one consultation room was not reviewed by the nurse between 24 April 2018 and the 28 May 2018.

- The cleaner attended one day per week and schedules for this were unavailable. Advice sought from a local general hospital IPC lead following the inspection confirmed that the cleaning products used (bicarbonate of soda and white vinegar) were inappropriate; as was the frequency of the cleaning regime. The clinic did not follow their own cleaning schedules which stated that toilets should be cleaned daily. The clinic did not have a waste disposal contract for the disposal of sanitary waste.
- Hand wash sinks were not available in the consultation rooms.
- Data sheets for the Control of Substances Hazardous to Health (COSHH) for use in the event of a chemical spillage or an allergic reaction were not available.
- The clinic did not have an up to date fire risk assessment, did not carry out documented checks on smoke alarms, did not conduct fire drills or check that emergency lighting was working properly. The clinic did not have a fire alarm system. This represented a serious risk to life, health and wellbeing as in the event of a fire the clinic could not assure themselves that patients could be safely evacuated.
- An induction programme had not been completed for any member of staff at the clinic. The recruitment procedures at the clinic did not keep people safe. The clinic could not provide appropriate assurance of good character or identification for the nurse or the registered manager (RM). The RM was not in possession of any records for the locum nurse, in post which would ensure a person was fit to work with patients. No Disclosure and Barring Service (DBS) record was in place, identification checks had not been undertaken. Additionally, there were no references or assurance of good character or training records in place for this nurse.
- Indemnity insurance for the nursing staff submitted post inspection did not cover the manufacture of vaccines and was limited to one million pounds.
- The provider could not assure themselves that checks were undertaken to ensure that the water systems in the clinic were safe. They did not undertake legionella testing checks, document the temperature of the water or ensure that rarely used outlets were flushed. This meant there was a risk that bacteria could enter the water system and be passed to the patient. The provider did not conduct the appropriate safety risk assessments.
- The Health and Safety policy at the clinic stated, 'the electricity supply is checked at least every five years by a competent person'. The registered manager was not aware of this and stated this had not been completed.
- The clinic undertook home visits where they administered treatment to patients including intravenous therapies. The clinic did not take emergency medicines or oxygen on these visits and had not risk assessed this. The clinic did not have a defibrillator located on the premises. We were told an informal agreement was in place with a neighbouring organisation to borrow their equipment. We were not assured that given a higher than average risk of patients experiencing anaphylaxis that this equipment would be available for use when required and the provider could not assure themselves it would be fit for purpose in an emergency. Up to date Resuscitation Council guidance was not in place and the clinic had not conducted a risk assessment for the emergency medicines it did not hold.
- The registered manager told us that medical equipment at the clinic had not been calibrated.
- A number of solutions marked, harmful, corrosive or hazardous were also viewed, stored on the floor of the vaccine preparation room. The door to this room was unlocked throughout the inspection.

Information to deliver safe care and treatment

Staff did not have the information they needed to deliver safe care and treatment to patients.

- Individual care records were hand written. We did not see that all the necessary information was contained within these records. The 'prescription' to authorise the

vaccines manufactured by the nurse were kept in a separate folder and we could not be assured that a prescription was available for each individual vaccine produced.

- Clinicians could not evidence that they used up to date evidence-based guidance. The nurse commented that she 'found this a nonsense'.

Safe and appropriate use of medicines

The systems in place for managing medicines did not keep patients safe.

- We reviewed the medicines management policy which covered the ordering, storage, dispensing and disposal of medicines. The policy stated unwanted medicines should be disposed of in a sharps bin, which was not appropriate and was not covered by the clinical waste management contract for the service. We asked the registered manager about this, and they told us they would return unwanted medicines to a local pharmacy for safe disposal.
- Staff at the clinic manufactured 'vaccines' made from allergens, preservatives and other pharmaceutical excipients. Medicines made in this way are referred to as 'specials' and are unlicensed. This production activity requires a Medicines and Healthcare Products Regulatory Agency (MHRA) Manufacturer's 'Specials' licence. However, the provider had not been granted a licence to manufacture vaccines. MHRA guidance states that unlicensed medicines may only be supplied against the valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine. Treating patients with unlicensed medicines represents a higher risk than treating patients with licensed medicines. This is because unlicensed medicines may not have been assessed for safety, quality and efficacy. Where patients were supplied with these medicines, no additional written information was provided and there was no entry in the clinical notes to confirm that the unlicensed nature of the treatment had been explained to the patient and they had given informed consent in accordance with GMC guidance.
- There was no standard operating procedure in place to guide staff how to manufacture vaccines, and the provider was unable to provide evidence that staff were suitably trained to perform this task. We found there was no quality control process in place to ensure the unlicensed vaccines were safe for patients to use. In addition, staff did not keep records of the batch number or expiry date of the excipients they had used to manufacture the vaccines, or details of the batches of vaccines themselves. This meant it would not be possible to identify which patients had received which batch of vaccines in the event of an adverse reaction, or when a medicine needed to be recalled. A vaccine production policy was in place which stated that solutions should be disposed of three months after production. We found stock solutions used to prepare vaccines which had been produced up to 22 years ago (one dated 1996). There was no scientific justification available to confirm the stability and sterility of these solutions or to confirm the effectiveness of the preservative used.
- Vaccines were supplied to patients to administer by injection at home. At our previous inspection in March 2018, we found the labels affixed to the vials of vaccine did not meet legal requirements. At this inspection we found labels had been updated to include dosage and administration instructions and the address of the clinic, however they did not include the date of dispensing. This meant that the legal requirements were still not being met.
- During our inspection, we found vials containing controlled drugs stored in a refrigerator in the clinic. The provider told us these were patients' own controlled drugs which had been formulated into stock solutions which were used to make up vaccines. There were no safe custody or record-keeping arrangements in place and this practice was not in accordance with The Misuse of Drugs Regulations. We raised this with the provider who assured us they would take immediate action to arrange for their safe disposal. We also viewed additional out of date medicines which were not stored appropriately and were out of date.
- Patients completed a questionnaire at their first consultation which included details of their medical history and any medicines they were already taking. Patients were sometimes asked for their consent to share details of their consultations and treatment with their registered GP. However, we found this was not always completed or actioned. Where patients gave

consent to the sharing of this information, we saw correspondence was filed with their medical notes. Patients were asked to complete a consent form before allergy testing and treatment was commenced. However, we found this was not repeated or updated when patients returned for subsequent testing or treatment. For example, one patient had attended the clinic in January 2018 and had given their consent for allergy testing to be performed. The patient re-attended on four further occasions and further allergy tests were carried out, however there was no record of consent having been obtained for these procedures.

- We asked the provider how they ensured appropriate antimicrobial use to optimise patient outcomes and to reduce the risk of adverse events and antimicrobial resistance. There was no evidence of audit or review of antimicrobial use, and no evidence that prescribing decisions were based on culture and sensitivity testing to ensure the most appropriate choice of treatment. The provider told us they prescribed combinations of antimicrobials, some of which were not licensed for use in the UK. This practice was not based on recognised local or national antimicrobial prescribing guidelines or best available evidence.
- On the day of inspection, we viewed a medicine where the packaging was written in a foreign language, and was not licensed for use in the UK. Staff we spoke with could not assure us that they were confident of the contents of this package.

Track record on safety

The service did not prioritise the safety of their patients.

- The service did not monitor or review activity. The service had not assessed the risks to patients who used the service and did not have an understanding of the risks to service users.

Lessons learned and improvements made

The service recorded significant events when things went wrong.

- There was a basic system for recording and acting on significant events. Incidents were recorded in the incidents book. A 'near miss' form was in place but we did not see that this had been used. The clinic had recorded two significant events since July 2017. We saw that action was taken but we did not see that changes to policy or procedure took place or evidence that learning was shared.
- The service had not acted on or learned from patient and medicine safety alerts. The service did not have an effective system in place to disseminate alerts to all members of the team or manage these safely. The registered manager showed us examples of some alerts issued by the MHRA. However, there was no record of the action taken in response. In addition, we found the clinic held concentrated potassium solution on the premises which they had previously administered to at least one patient. This practice is unsafe and is no longer recommended, and was the subject of a national patient safety alert which was issued in 2002.
- The provider had a mercury sphygmomanometer (blood pressure monitoring machine) on the premises. They did not have the appropriate systems in place to ensure staff and patient safety in the event of a mercury spillage. An alert issued in 2013 for medical devices containing mercury, stated that appropriate health and safety procedures should be implemented including mercury spillage kits and staff training to ensure safe handling of these devices. The provider did not have these arrangements in place.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was not providing effective care in accordance with the relevant regulations.

The inspection highlighted serious deficiencies in the effectiveness and quality of care provided which posed a significant risk to the life, health or wellbeing of patients.

We did not see evidence of up to date research guiding practice or medicines being prescribed in line with current guidance. Clinicians at the clinic did not carry out any quality improvement activity.

Effective needs assessment, care and treatment

The provider did not have systems in place to keep clinicians up to date with current evidence based practice. Clinicians did not assess needs or deliver care and treatment in line with current legislation, standards and guidance.

- Antimicrobials prescribed at the clinic were not in line with local or national formal guidance. There was no apparent assessment made as to the risks of developing antimicrobial resistance. Antimicrobials were prescribed without undertaking culture or sensitivity tests.
- We asked a clinician how they would keep themselves up to date with current evidence based practice. The clinician replied that they 'found this a nonsense'. They also confirmed that the clinic did not conduct any audit of the outcomes for patients.
- Arrangements were in place to deal with patients attending for repeat appointments. Appointments were allocated based on treatment regimes and at the request of patients.

Monitoring care and treatment

- The medical director of the Airedale Allergy Centre told us they did not carry out any quality improvement activity or conduct any audits.

Effective staffing

Staff did not have the skills, knowledge and experience to carry out their roles.

- We did not see that any member of staff had completed all the necessary training as noted in the clinic's own staff training policy.
- We saw that an induction policy was in place which included reference to actions to be taken prior to a new member of staff commencing employment. However, the practice had failed to follow this policy and could not evidence any completed induction check lists.
- On the day of inspection, the clinic could not evidence two references, identification, previous employment history or indemnity insurance for the clinic nurse. Records for the Registered Manager (RM) were also incomplete. We saw that a recently requested Disclosure and Barring Service (DBS) checks for both the Nurse and the RM had not yet been returned. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable.)
- The RM could not evidence that any recruitment checks had been undertaken prior to the appointment of a locum nurse who worked between one and two days per week. The RM could not evidence a training record for this person, a DBS check, evidence of conduct in a previous employment or identification.
- Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC)/ Nursing and Midwifery Council.
- The provider did not demonstrate an understanding of the learning needs of staff and a comprehensive record of skills, qualifications and training was not maintained.

Coordinating patient care and information sharing

- One patient told us that they were receiving care at the Airedale Allergy Centre and a sister clinic. The patient ordered medicines from the Airedale Allergy Centre despite not having been tested there for two years and stated they were unsure if the dose of the medicine they were receiving was correct.
- Patient information was not shared in accordance with the wishes of patients. We viewed several examples of patient records where the patient had consented to share the information regarding their consultation with their GP. This information was inconsistently shared.
- We did not see that serious consideration was given to the mental health needs of patients. The medical director told us that they would regularly see patients with a mental health condition but these concerns were secondary to their underlying allergy issues.

Supporting patients to live healthier lives

Are services effective?

(for example, treatment is effective)

Staff were not consistent or proactive in empowering patients

- We were told that where appropriate, staff gave people advice so they could self-care. We did not see evidence of care plans for patients or suitable patient leaflets that explained their own personal regime or the treatment being undertaken.
- When the clinic was closed, patients were requested to contact their own GP or the emergency department.

Consent to care and treatment

The service did not obtain consent to care and treatment in line with legislation and guidance.

- We were not assured that staff we spoke with understood the requirements of legislation and guidance when considering consent and decision making, despite undertaking recent training in this area.
- We reviewed medical records for one patient. During the consultation, a clinician had recorded the patient was "not aware of why they were at the clinic" and that the patient "appeared very vague". There was no record of an assessment of the patient's mental capacity to consent to the procedure. The clinic had continued to treat the patient despite later receiving information from the patient's registered GP who had written to the clinic to inform them the patient suffered from a relevant, serious mental health disorder. At ongoing consultations no further consideration had been given to the patients' ability to consent; nor had an assessment of their mental capacity been carried out.

Are services caring?

Our findings

We found that this service was not providing caring services in accordance with the relevant regulations.

The inspection highlighted serious deficiencies in the quality of care provided, which posed a significant risk to the life, health or wellbeing of patients.

Airedale Allergy Centre by omission, did not demonstrate a caring attitude towards the health and wellbeing of patients.

Kindness, respect and compassion

- Feedback from patients was positive about the way staff treated people
- We identified serious failings during the inspection on 12 March 2018 and on the 16 October 2018. We were not assured that given the lack of response and understanding of these issues by the provider that patients were treated with respect.

Involvement in decisions about care and treatment

We were not assured that staff helped patients to be involved in decisions about care and treatment.

- Patient records showed that up to date medical histories, consent and capacity assessments were not routinely reviewed or undertaken. Therefore; we could not be assured that patients were supported to make appropriate decisions regarding their care and treatment.
- We did not see any information that was available in an easy read format.
- Patients told us through comment cards, that they felt listened to and supported by staff and had sufficient time during consultations.

Privacy and Dignity

The service did not respect patients' privacy and dignity.

- The deficiencies found at the Airedale Allergy Centre led inspectors to conclude that clinicians and staff did not respect the privacy and dignity of patients. During the day of inspection, we consistently saw that a consultation room door where a patient was receiving treatment was ajar.
- The clinic did not provide a waiting area. Patients were asked to sit on chairs in the hallway if clinicians were seeing other patients.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was not providing responsive care in accordance with the relevant regulations.

The inspection highlighted serious deficiencies in the responsiveness and quality of care provided which posed a significant risk to the life, health or wellbeing of patients.

The service did not routinely review the health status of patients or respond to feedback from patients and other relevant health professionals.

Responding to and meeting people's needs

The service did not organise or deliver services to meet patients' needs.

- The provider did not routinely update the medical history of their patients. Patient notes viewed on the day of inspection showed that this was sporadic. Therefore, clinicians could not be assured that they were responding to changing patient's needs.
- The facilities and premises were not appropriate for the services delivered. We did not see that the vaccine preparation room was locked at any point during our inspection. Refrigerators were not lockable; and vaccines and medicines, including controlled drugs, were potentially accessible to patients.
- The clinic had conducted a patient survey in 2018. They asked 40 patients for their opinions and six responses were received, the clinic did not respond to this patient feedback or make changes to how services were delivered.
- The clinic requested that patients completed an 'End of treatment' questionnaire. We saw that 19 responses had been collected since 2015. No audit of these findings had been undertaken, there was no response to these findings and no action plan was in place.

Timely access to the service

Patients were able to access care and treatment from the service within an appropriate timescale for their needs.

- We were told that patients could see a clinician within two to three weeks of requesting an initial appointment.
- Patients had access to initial assessment, test results, and treatment.

Listening and learning from concerns and complaints

The service did not consistently take complaints and concerns seriously and did not always respond to them appropriately.

- The centre did not respond appropriately to concerns raised by a fellow health professional regarding the capacity and mental ill health of a patient.
- Information about how to make a complaint or raise concerns was available and a policy was in place. We saw that where a patient had complained about a consultation and the service offered, that the clinic had refunded the cost of the consultation.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

We found that this service was not providing well-led care in accordance with the relevant regulations.

The inspection highlighted serious deficiencies in the governance and quality of care provided which posed a significant risk to the life, health or wellbeing of patients.

The provider and the registered manager demonstrated a lack of insight and oversight as to the requirements of managing the work to be performed. They had failed to ensure that systems and processes were in place to assess, monitor, and improve the quality and safety of the service provided at Airedale Allergy Centre.

Leadership capacity and capability;

Leaders did not have the capacity and skills to deliver high-quality, sustainable care.

- The medical director of the service was only present at the clinic for three days over a four-week cycle. Staff told us they would text him if they needed help or contact staff at another location.
- The provider had did not have an effective process in place to develop leadership and skills within the team.

Vision and strategy

- The service did not discuss their vision or strategy with the inspection team.

Culture

The service did not promote a culture of high-quality sustainable care.

- The service told us that they focused on individual patient needs. However, we did not see that patient needs were individually or appropriately considered, reviewed or assessed.
- We did not see that staff had been supported to develop the appropriate skills necessary to undertake their roles. The clinic nurse was referred to as an 'allergy nurse'. No specific training for this role was recorded with the nursing and midwifery council and we were told that all training that had been undertaken was in-house. We were not shown any evidence of this.
- Staff had received an appraisal in the last year. However, we did not see that clinicians were given protected time for professional development or evaluation of their clinical work. The nurse at the clinic did not participate in clinical supervision or reviews with peers.
- We were told that staff were not given protected time for stock ordering and rotation or completing tasks and cleaning schedules.

Governance arrangements

Systems were not in place to support good governance or management.

- Structures, processes and systems to support good governance and management were not appropriate.
- A newly reviewed suite of policies was in place. However, we identified that the clinic was not following their own policies to ensure safety and that the clinic was not operating effectively. For example; the clinic was not following their own policies for medicines management, safeguarding, infection prevention and control, fire, recruitment and training.

Managing risks, issues and performance

There was no clarity around processes for managing risks, issues and performance.

- Processes were not in place to enable the clinic to identify, understand, monitor or address current and future risks including risks to patient safety.
- The provider did not undertake any audits of consultations, prescribing or referral decisions contrary to their clinical audit and medicines management policies.
- Leaders at the clinic could not demonstrate the appropriate management or oversight of all relevant safety alerts.
- The provider did not undertake any quality improvement activity at the Airedale Allergy Centre location.
- The provider did not ensure that basic safety measures such as fire checks, legionella assessment and necessary suitable risk assessments in relation to emergency medicines and the use of a defibrillator were in place or effective.
- Staff were not trained to manage major incidents.

Appropriate and accurate information

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

The service did not act on appropriate and accurate information.

- The provider did not use or review any quality or operational information to improve performance, they did not review the quality of care delivered to patients.
- During our inspection we requested minutes of relevant staff meetings. These were not forwarded to the inspection team. We did not see evidence that quality and sustainability were discussed by the team.
- We saw that ineffective arrangements were in place for the management of patient data. For example, signed prescriptions were not kept in patient notes but were held in a file in the preparation room. A review of patient records found that an authority to supply unlicensed medicines was not available in all patient records.

Engagement with patients, the public, staff and external partners

The provider had requested feedback from patients but had not responded to or reviewed this.

- The clinic had conducted a patient survey in 2018. They asked 40 patients for their opinions and six responses were received, the clinic did not respond to this patient feedback or make changes to how services were delivered.
- The clinic requested that patients completed an 'End of treatment' questionnaire. No audit of these findings had been undertaken, there was no response to these findings and no action plan was in place.
- We did not see that the provider engaged with external partners to support high-quality sustainable services. The medical director told us he had attended conferences.
- Staff told us that meetings were held but we did not receive any evidence of this or of what was discussed.
- The service could not evidence the effectiveness of the treatments it offered.

Continuous improvement and innovation

There was no evidence of systems and processes for learning, continuous improvement or innovation.