Hightree Medical Limited

Hightree Clinic

Inspection report

Hightree House,
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Uckfield,
East Sussex,
TN22 5QL
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Website: www.hightreemedical.com

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Overall summary

We carried out an announced comprehensive inspection on 9 October 2018 to ask 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 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 was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

This service is 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 exemptions from regulation by CQC, which relate to particular types of regulated activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Hightree Clinic is an independent doctor service. They provide consultation, treatment and prescribing services for conventional and complementary medicine, with an aim to improve and/or sustain patients' overall quality of life. The clinic offers consultation and treatment only to patients over the age of 18.

Hightree Clinic provides a range of complementary therapies, for example medical acupuncture and osteopathy, which are not within CQC scope of registration. Therefore, we did not inspect or report on these services.

The lead GP is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like

Summary of findings

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.

We received 12 completed Care Quality Commission comment cards. Feedback from patients was consistently positive. We received comments that the staff were friendly, kind and put them at ease. They commented that the service received was supportive, caring, informative and efficient. Many patients described how they had used the service on several occasions.

Our key findings were:

- The registered manager recognised that the current systems and processes at the clinic needed updating or improvement. They had identified gaps in compliance with regulation and throughout the inspection we recognised some improvements were planned or underway.
- We found that the processes to identify, understand, monitor and address current and future risks including risks to patient safety were not yet well implemented. For example, the recording and oversight of safety alerts, significant events and complaints.
- We found that patients' medical records were not always clear, comprehensive and legible. We noted that not all records contained information we would expect to see about the consultation and treatment plan. We could not be assured that they always prescribed, administered and supplied medicines to patients in line with legal requirements.
- Risks to patients, staff and visitors to the clinic were not always assessed or well managed. This included; the systems to manage infection prevention and control (IPC), the completion of recruitment checks, and comprehensive risk assessments being carried out in relation to safety issues.
- There was limited evidence of quality improvement activity to review the effectiveness and appropriateness of the care provided. We did not see any clinical audits to monitor the quality of prescribing for instance.
- The facilities and premises were appropriate for the services delivered.
- Feedback from patients was consistently positive. Patients said they were treated with compassion, dignity and respect and they were involved in their care and decisions about their treatment.
- We found that policies and procedures were not all specific to the clinic, regularly reviewed or contained up to date information.
- There was a clear leadership structure and staff felt supported. The clinic proactively sought feedback from staff and patients.

We identified regulations that were not being met and the provider must**:**

- Ensure care and treatment is provided in a safe way to patients.
- Establish effective systems and processes to ensure good governance in accordance with the fundamental standards of care.
- Ensure persons employed in the provision of the regulated activity receive the appropriate support, training, professional development, supervision and appraisal necessary to enable them to carry out the duties.
- Ensure service users, or a person acting on the service user's behalf, are provided with written information about any fees, contracts and terms and conditions, relating to the cost of their care or treatment.

You can see full details of the regulations not being met at the end of this report.

Professor Steve Field CBE FRCP FFPH FRCGPChief Inspector of General Practice

Hightree Clinic

Detailed findings

Background to this inspection

Hightree Clinic is an independent doctor service. They provide consultation, treatment and prescribing services using conventional and complementary medicine. The clinic aims to address the physical, nutritional and well-being needs of patients in order to improve their health and aid recovery. The clinic offers comprehensive health diagnostics and assessments, for example screening tests for a wide spectrum of infections, deficiencies and hormone imbalances. Services include intravenous treatments for nutritional deficiencies, oxygen therapy (such as medical ozone), local and whole-body hyperthermia. They also offer treatments for musculoskeletal disorders, including joint injections.

The clinic address is:

Hightree House,

Eastbourne Road,

Uckfield,

East Sussex,

TN22 5QL

The clinic is open between 9am to 5pm on a Monday, Tuesday, Thursday and Friday.

Registered services are provided by one GP, a receptionist and a healthcare worker (in training). The registered manager had also employed a consultancy agency to assist with improving and streamlining their governance arrangements.

We carried out an announced comprehensive inspection at Hightree Clinic on 9 October 2018. Our inspection team was led by a CQC lead inspector who was accompanied by a CQC GP specialist adviser.

Prior to this inspection we reviewed a range of information that we hold about the service, including information gathered by the provider from a pre-inspection information request.

During our visit we:

- Spoke with a range of staff, including the lead GP, the healthcare worker and two members of the consultancy agency.
- Reviewed comment cards where patients and members of the public shared their views and experiences of the service.
- Made observations of the internal and external areas of the main premises.
- Looked at information the clinic used to deliver care and treatment plans.
- Reviewed documentation relating to the clinic including policies and procedures.

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 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 because:

- Not all staff had received safeguarding children training and polices did not contain up to date information.
- There was no fire risk assessment and no evidence of fire drills.
- Not all staff had received appropriate infection control training and there were no cleaning logs for equipment used. There was no completed infection control audit or legionella risk assessment.
- Recruitment files did not all contain required information.
- Consultation notes were not always clear, comprehensive and legible. Not all records contained information we would expect to see about the consultation and treatment plan.
- The provider could not demonstrate that they always prescribed, administered and supplied medicines to patients in line with legal requirements.
- The provider did not always follow or work to national guidance, such as NICE (National Institute for Health, Care and Excellence). They did not evidence the guidance used or a written rationale for the approach when it was not to national guidance.
- There was no evidence of how safety alerts received would be recorded, actioned or shared with staff.
- Not all staff demonstrated an understanding of significant events.

Safety systems and processes

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

- The provider had some systems to safeguard children and vulnerable adults from abuse. We viewed the training records for the GP and two staff. We saw they had received up-to-date adult safeguarding training appropriate to their role. The clinic only offered consultations and treatments to patients over the age of 18. However, it was unclear whether children were attending with adults during their treatment and whether this had been risk assessed, or what the clinic policy was for their supervision. They had a designated lead for safeguarding. We saw the policy, which contained safeguarding information for both adults and children, had been reviewed in April 2018. However, this did not contain up-to-date information. The policy outlined who to go to for further guidance and were accessible to all staff. Although the policy specified that all staff should receive child safeguarding training every two years, we found that not all staff had received recent training. Staff we spoke with demonstrated an understanding of how to identify and raise a safeguarding concern. Staff who acted as chaperones were trained for the role and had received a DBS check.
- The service worked with other agencies to support patients and protect them from neglect and abuse. Staff took steps to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- A range of safety risk assessments had been conducted to ensure that facilities and equipment were safe and in good working order. However, we found that not all of these were complete. The provider had ensured that that all equipment was maintained according to manufacturers' instructions, and electrical safety checks had been carried out. Fire alarms and equipment checks were carried out and a fire procedure was in place. However, the provider had not conducted a fire risk assessment and they could not demonstrate fire drills had been completed.
- The clinic maintained appropriate standards of cleanliness and hygiene. We observed the premises to be clean and tidy. The clinic had a general cleaning schedule and we saw that all cleaning of the premises was recorded. The lead GP was the infection prevention and control (IPC) lead. Not all staff had received appropriate IPC training. We were told that clinical equipment was cleaned after use, however this was not recorded. They had not completed an infection control audit within the last year. They offered shower facilities to patients that were within the lead GPs own home, but did not provide a risk assessment for this in terms of patient safety or infection control. The provider had COSHH (control of substances hazardous to health) data sheets for the products in use but we noted a risk assessment was not dated, therefore it was unclear when it was completed. Although there were systems to manage healthcare waste, we saw one of the sharps bins was not sited safely and the label had not been completed correctly, to enable safe disposal. The provider told us that they had a new healthcare worker who would be taking on responsibility of IPC in future.

Are services safe?

- The provider evidenced water testing had been undertaken in May 2018, which showed there was no Legionella present. (Legionella is a term for a particular bacterium which can contaminate water systems in buildings). However, no risk assessment had been undertaken by an external body as per their policy dated March 2016. The provider did not demonstrate that mitigating actions had been implemented such as water temperature testing and regular flushing of water outlets to minimise risks. Following our inspection, the provider told us they completed these mitigating actions routinely, however we were not provided with additional documentary evidence to demonstrate this.
- The provider told us they carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. We reviewed two staff files and found one file did not contain evidence of employment history or a signed contract. Disclosure and Barring Service (DBS) checks were undertaken where required. (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).

Risks to patients

There were systems to assess, monitor and manage risks to patient safety.

- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an effective induction system for agency staff tailored to their role.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. Staff told us they received annual basic life support training but this was not evidenced in one out of two of the staff files we looked at. There were emergency medicines readily available. These were easily accessible to staff in a secure area of the clinic and all staff knew of their location. All the medicines were checked monthly, were in date and stored securely. The clinic had a defibrillator available on the premises and oxygen with adult masks. The defibrillator pads, battery and the oxygen were all in date and the oxygen cylinder was full. A first aid kit and accident book were available. The guidance for emergency equipment was in the Resuscitation Council UK guidelines.
- The provider evidenced that appropriate indemnity arrangements were in place to cover all potential liabilities.

Information to deliver safe care and treatment

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

- Individual care records of consultations and treatment were hand written. We found that clinical records were not always clear, comprehensive and legible. The care records we saw did not always contain information we would expect to see. For example evidence of physical examination or basic health monitoring before, during or after treatment. We reviewed records of patients notes that did not always comprehensively describe the consultation, including whether this was face to face or a telephone consultation. This meant that information to deliver safe care and treatment was not always available to relevant staff in an accessible way. Following our inspection the provider told us they intended to audit the clinical records of patients to ensure they contained information including; the clinic consent form, health form and allergies.
- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment. We saw evidence that the service used consent forms to record whether a patient agreed to information being shared with their usual GP.
- The paper records were stored in locked filing cabinets and the service had a system in place to retain medical records in line with guidance. They told us they were planning to create a database to store records electronically.
- We saw evidence that the lead GP made appropriate and timely referrals to other services where required.

Safe and appropriate use of medicines

The service had some systems for appropriate and safe handling of medicines.

- Some of the systems and arrangements for managing medicines, including emergency medicines and equipment, minimised risks. The service kept prescription stationery securely and monitored its use. The prescriptions we reviewed had been written in line with legal requirements. This included the medicine name, form, strength, dose and quantity.

Are services safe?

- The provider told us they had not yet completed any medicines audits, to ensure prescribing was in line with best practice guidelines for safe prescribing.
- The service dispensed a selection of medicines, vitamins and herbal remedies. They were stored securely within an open dispensing area. All cupboards and the medicines fridge were locked. The lead GP was responsible for the dispensary. We were told that medicines were always checked carefully for accuracy, by two separate staff before being supplied to patients by the lead GP. There were no controlled drugs on the premises. We found that appropriate monitoring was taking place of the medicines stored in the fridge. This included that two thermometers were used and the service recorded daily checks of the temperature.
- Processes were in place for checking medicines and staff kept accurate records of medicines. We saw that the service monitored and recorded all medicines stocked at the clinic.
- The provider did not always follow or work to national guidance, such as NICE (National Institute for Health, Care and Excellence). For example, the provider was not following national guidance for patients with chest infections. The provider, when asked, did not evidence the guidance used or a written rationale for the approach when it was not to national guidance. The provider told us that any treatment offered would be fully discussed with the patients, including the benefits, risks and potential side effects. Following our inspection the provider sent us a number of internet links to sources of information, only to explain their rationale for using high dose intravenous vitamin C as a treatment for cancer. These sources were not nationally approved or recognised guidance. We were not sent any additional evidence or information regarding the remaining scope of treatments offered at the clinic.
- The provider did not demonstrate that they always prescribed, administered and supplied medicines to patients in line with legal requirements. For example, we saw evidence of routine medicine being administered with no recorded dose in the patients' clinical notes.
- There were arrangements in place to check the identity of patients.

Track record on safety

The service did not have a good safety record.

- Risk assessments were not evidenced for fire, legionella by an external body, or health and safety. We viewed the records of two staff files and one staff member had received fire safety training. Fire extinguishers were in place but fire drills had not been carried out. Lone working was in place but had not been formally risk assessed.
- The provider told us they had recently made arrangements to receive patient safety alerts, recalls and rapid response reports issued through the Medicines and Healthcare products Regulatory Authority (MHRA). They could not yet demonstrate compliance with these alerts, including how they would be recorded, actioned and shared with all staff. Following our inspection, the provider told us they obtain safety alerts and discuss with staff if relevant. However, we were not provided with additional documentary evidence to demonstrate how they were recorded, actioned and disseminated to staff.

Lessons learned and improvements made

The service had systems in place to learn and make improvements when things went wrong, but these were not all well implemented.

- The provider had recently started to update their systems for recording, acting on, analysing and learning from significant events. A template was being created to record incidents and they planned to discuss any events in a monthly staff meeting. They told us they had not had any significant events or unexpected or unintended safety incidents. Staff told us they would record such incidents in their accident and injury book.
- Staff understood their duty to raise concerns and report incidents and near misses. However, we found that not all staff demonstrated their understanding of significant events. Leaders told us they would support them when they did so.

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 because:

- Care plans were not consistently completed for each patient.
- There was limited evidence of quality improvement activity.
- Not all staff had received regular appraisal and training appropriate to their role. This included Mental Capacity Act 2005 training.
- Details of costs for consultation and treatment were provided to patients verbally only.

Effective needs assessment, care and treatment

The provider was aware of evidence based guidance and had access to written guidance should this be required. For example, NICE (National Institute for Health and Care) guidance.

The provider had recently made arrangements to receive new guidance.

The lead GP told us they assessed needs and delivered care and treatment, in line with relevant standards and guidance. However, we were not provided with evidence of these standards and guidance.

- The provider told us that patients' immediate and ongoing needs were assessed. Where appropriate this included their clinical needs and their mental and physical wellbeing. We saw that the service used a care plan template to record information about the patient. This including their clinical history, medicines being taken and known allergies. It also included the treatment plan such as frequency of treatment and monitoring tests to be completed. We found this was not consistently completed for each patient.
- Due to the record keeping at the service, it was not clear whether enough information was always obtained to make or confirm a diagnosis.
- We saw no evidence of discrimination when making care and treatment decisions.
- Arrangements were in place to deal with repeat patients. Patients could request repeat medication over the telephone. The lead GP then conducted a telephone consultation prior to issuing a prescription. Prescriptions were emailed directly to the chemist to maintain security.
- Staff assessed and managed patients' pain where appropriate.

Monitoring care and treatment

There was limited evidence of quality improvement activity to review the effectiveness and appropriateness of the care provided.

- There was a lack of documentary evidence to demonstrate that any clinical audits leading to quality improvement had been completed recently.
- Since the inspection the provider has sent evidence of a two-cycle audit dated March 2011, which demonstrated an improvement in the number of patients who were contacted within certain timescales following treatment for thyroid disorders at the clinic.
- In future they hoped to employ a research assistant to capture evidence that demonstrated the impact treatments had on outcomes for their patients.
- The care records we saw did not always contain basic health monitoring of the patient before, during or after treatment. For example, blood pressure or pulse. The provider told us that outcomes for patients were not always measurable and included subjective evidence of improvement, for example energy levels, mental wellbeing or pain and swelling.

Effective staffing

Not all staff had the skills, knowledge and experience to carry out their roles.

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff. The lead GP was registered with the General Medical Council (GMC) and was up to date with revalidation.
- The lead GP had joined a learning set with other GPs in the local area. They met monthly to discuss clinical issues and cases, professional development and practical help such as procurement. The lead GP was also part of a group of GPs who worked in alternative medicine.
- The provider could not demonstrate that all established staff consistently received training and guidance in such topics as basic life support, fire safety, information

Are services effective?

(for example, treatment is effective)

governance and infection control. One of the staff members was still completing their induction program, therefore had not yet completed all training requirements.

- Staff were encouraged and given opportunities to develop. They told us training needs were identified informally throughout the year.
- The provider told us they planned to complete appraisals for all staff. Following our inspection the provider told us they completed appraisals annually, however we were not provided with additional evidence to demonstrate this.

Coordinating patient care and information sharing

Staff worked together, and worked with other organisations, to deliver care and treatment.

- The service offered extended diagnostic services and worked with other providers where applicable. For example, bodily fluid was screened for a wide spectrum of infections, deficiencies and hormone imbalances. The analysis was conducted by various external laboratories around the world, including USA, Germany and Netherlands. They also referred effectively to other services for ultrasounds, ECGs (electrocardiography) and x-rays. The provider coordinated these results in order to provide holistic and person-centred care to their patients. All blood test results were checked by the lead GP who gave the patient their results, either over the telephone or in person at a consultation.
- Staff communicated effectively with other services when appropriate. For example, the provider liaised with patients GPs and external healthcare providers. We saw evidence of a letter sent to a patients' GP requesting the patient be monitored and this was signed by both the patient and service.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. We saw evidence that the provider shared appropriate information when the patient had agreed to this.

Supporting patients to live healthier lives

Staff were consistent and proactive in empowering patients, and supporting them to manage their own health and maximise their independence.

- Where appropriate, staff gave patients advice so they could self-care. Staff encouraged and supported patients to be involved in monitoring and managing their own health.
- The service identified patients who may be in need of extra support. They gave them more time and encouraged them to discuss their needs and share information with their general practitioner.
- The provider told us they often assisted patients who were anxious and helped those who were concerned due to not understanding their diagnosis. They told us they empowered patients to speak with their own GP or specialist.
- Where patients' needs could not be met by the service, staff redirected them to the appropriate service.

Consent to care and treatment

The service obtained consent to care and treatment.

- Not all staff, including the lead GP, had completed Mental Capacity Act 2005 training, to ensure that they acted in a patient's best interest.
- We saw evidence of verbal and written consent being obtained. We saw the service used a general consent form and one for investigation or treatment. We saw this included an explanation that treatment provided by the clinic, often complementary medicine, were not always tested or verified as with evidence based medicine. Patients were asked to sign the form to agree they had read and understood the information. We saw these evidenced within patient notes.
- We were told that patients were provided with all the information, including costs, they required to make decisions about their treatment prior to treatment commencing. However, costs for consultation and treatment were provided verbally only. Costs had not been displayed at the clinic or on the Hightree Clinic website. We asked to see a written pricing schedule and found this to be partially typed with some handwritten information. The provider told us this was in the process of being updated.

Are services caring?

Our findings

We found that this service was providing caring services in accordance with the relevant regulations.

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- Feedback from patients was positive about the way staff treat people. The service used their own feedback form that was given to every patient. They told us the results were usually positive.
- We received 12 completed comment cards. Feedback was consistently positive. We received comments that the staff were friendly, kind and put them at ease. They commented that the service received was supportive, caring, informative and efficient. Many patients described how they had used the service on several occasions.
- There were five reviews on Facebook and each review was rated as five stars. They had also received two recommendations.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information.

Involvement in decisions about care and treatment

Staff helped patients to be involved in decisions about care and treatment.

- Interpretation services were available for patients who did not have English as a first language. The service also had staff members who spoke additional languages, including German and Polish.
- Patients told us through comment cards, that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decision about the choice of treatment available to them. They commented that the lead GP provided excellent care and treatment.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- We did not see any patients during the inspection. However, staff gave assurances that doors were closed during consultations and conversations taking place in these rooms could not be overheard. Equipment used to treat patients was mostly in the clinical rooms to protect the privacy and dignity of patients, including for whole body hyperthermia and oxygen therapy. The communal area was used for patients receiving intravenous treatment, where they that had consented to this. However, privacy screens were available to patients if required.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was not providing responsive services in accordance with the relevant regulations because:

- The provider did not have clear systems and processes to ensure that complaints were always thoroughly recorded, acted on, analysed and appropriately stored.

Responding to and meeting people's needs

The provider understood the needs of their patients and the alternative therapy community. They had used this understanding to fill health care gaps, support additional services and meet patient needs.

- The clinic mainly saw patients with long term conditions, cancer, Lyme disease and thyroid conditions. The majority of patients, approximately 30, were treated for thyroid conditions. The provider had arrangements in place to meet the needs of these patients by offering telephone consultations and reviews.
- The clinic was open between 9am to 5pm on a Monday, Tuesday, Thursday and Friday. Walk in patients were also accepted. Appointments could be booked over the telephone or in person.
- Most of the patients attending the clinic had referred themselves for treatment. Some had been referred or recommended to the clinic by charity organisations.
- The facilities and premises were appropriate for the services delivered. Many patients commented within CQC comment cards that the clinic was in a relaxing and pleasant environment.

Timely access to the service

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

- Patients had timely access to initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients with the most urgent needs had their care and treatment prioritised. The provider told us that patients were seen within one to two weeks, depending on priority.

Listening and learning from concerns and complaints

The service told us they took complaints and concerns seriously and would respond to them appropriately to improve the quality of care. However, we found that the systems and processes for investigating, acting on and responding to complaints were not clear.

- The provider told us they had not received any verbal or written complaints. Staff told us they would treat patients who made complaints compassionately.
- We were told that the consultancy agency was the lead for complaints who would conduct the investigation and response. They told us that written complaints would be added to the patient notes and verbal complaints would be added to a communication book.
- The service had a complaints policy in place that had been recently reviewed. However, we found the clinic was not following their own policy. For example, it did not state that complaints would be investigated by the consultancy agency. The policy also contained a complaints template to be used for recording all complaints.
- The service told us they intended to learn lessons from individual concerns and complaints. They planned to conduct analysis of trends.

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 because:

- We were not provided with evidence of a business plan, vision or strategy.
- Policies and procedures were not all specific to the clinic, regularly reviewed and containing up to date information.
- The processes to identify, understand, monitor and address current and future risks including risks to patient safety were not always clear or well implemented.

Leadership capacity and capability;

The registered manager (the lead GP) recognised that the current systems and processes needed improvement.

- The provider demonstrated an understanding of issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them. For example, they had employed the services of a consultancy agency to help them improve systems and processes at the clinic. They had identified gaps in compliance with regulation and throughout the inspection we recognised improvements were underway.
- Staff we spoke with told us the registered manager was visible and approachable.

Vision and strategy

The service had a vision and strategy to deliver high quality care and promote good outcomes for patients, but this was not well documented.

- The provider told us their objective was to provide holistic and patient centred care generally to those with chronic disease, cancer, Lyme's disease and thyroid conditions. They aimed to use to help patients when other treatments had failed or treatment options had been exhausted. They said they would do so while remaining transparent, courteous and professional with other colleagues and services involved with patients.
- The provider described priorities in terms of the future sustainability and development of the service. For example, they told us about their plans for extension of the clinic to increase storage capacity and to add a bathroom to provide shower facilities for patients. They also were exploring options available such as partnership working in the future. However, we were not shown a supporting business plan as to how they would achieve their priorities.

Culture

The service had a culture of high-quality sustainable care.

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients.
- The registered manager acted on behaviour and performance inconsistent with the vision and values.
- Staff we spoke with told us they were able to raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes in place, or planned, for providing all staff with the development they need. This included appraisal and career development conversations. All staff were considered valued members of the team. They were given protected time for training and for professional development. Staff we spoke with told us they felt encouraged and inspired by the registered manager.
- The provider did not always demonstrate a strong emphasis on the safety and well-being of all staff. For example, the provider did not demonstrate that comprehensive risk assessments in relation to safety issues, including for health and safety, had been carried out.

Governance arrangements

The responsibilities, roles and systems of accountability to support good governance and management were not always clear.

- Structures, processes and systems to support good governance and management were not all clearly set out, understood and effective.
- Staff were clear on their roles and accountabilities
- The provider had not established policies, procedures and activities to ensure safety and did not demonstrate that they assured themselves that they were operating

Are services well-led?

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

as intended. We found that policies and procedures were not all specific to the clinic, regularly reviewed and containing up to date information. For example, the medical emergencies policy directed staff to a health and safety officer, but staff told us during interviews that they were unsure who this was. The disaster handling and business continuity planning policy last reviewed in March 2016 described that a disaster recovery box was held off site, but the named staff member on the policy had retired. We saw and were told by staff that the policies and procedures were all in the process of being updated and streamlined. Following inspection, the provider told us that all staff were aware that the health and safety contact is the lead GP.

Managing risks, issues and performance

There was a lack of clarity for the processes for managing risks, issues and performance.

- We found that the processes to identify, understand, monitor and address current and future risks, including risks to patient safety, were not always clear or well implemented. For example, the recording and oversight of safety alerts, significant events and complaints.
- A lack of risk assessment and evidence of monitoring meant that quality and operational information was not always available to ensure and improve performance.
- There was no evidence of a quality improvement programme or continuous clinical and internal audit in place to monitor quality and to drive improvements. Clinical audit was limited and infection control audits were not carried out. We did not see any clinical audits to monitor the quality of prescribing.

Appropriate and accurate information

It was not clear whether the provider always acted on appropriate and accurate information.

- The provider did not demonstrate that quality and operational information was used to ensure and improve performance.
- There was some evidence that quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.
- There were not always effective arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems. This included patients' medical records which were often illegible and of a variable standard. We noted that not all records contained information we would expect to see about the consultation and treatment plan.
- We were told that the clinic had started a process to comply with regulation and to become in line with new data protection legislation (the General Data Protection Regulation or GDPR). We saw they had sent a letter to all patients requesting them to complete a consent form, an update of allergies and medical precautions, details of their own GP and any feedback.

Engagement with patients, the public, staff and external partners

The service involved the public and staff to support high-quality sustainable services.

- The clinic had a system in place to gather feedback from patients using a feedback form, which was given to each patient. We saw the form included questions about the clinic environment and the consultation or treatment. Staff told us that feedback from patients was positive and they planned to put systems in place to further analyse the data.
- Staff were able to describe to us the systems in place to give feedback. This included informal discussion and staff meetings. We were told there was a staff meeting at the end of every day to discuss any issues, and to handover enquiries or concerns to the lead GP. We saw minutes of a team meeting held in October 2018 to discuss a new approach; this included methods of communication and standards for setting up a new patient record. It was agreed they would have full staff meetings every month.

Continuous improvement and innovation

There was a focus on continuous learning and improvement across all staff at the clinic. The provider passionately described research within the area of integrated medicine. They aimed to provide innovative and pioneering medicine.

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
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing How the regulation was not being met: • The provider was unable to demonstrate that all staff received regular appraisal of their performance in their role from an appropriately skilled and experienced person and therefore any training, learning and development needs identified, planned for and or supported. • The provider was unable to demonstrate effective systems and processes to ensure that suitably qualified, competent, skilled and experienced persons were deployed. We found that appropriate recruitment checks had not been undertaken prior to employment of all staff. This was in breach of regulation 18(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulation

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 19 CQC (Registration) Regulations 2009 Fees How the regulation was not being met: • The provider did not ensure that service users, or a person acting on the service user's behalf, were always provided with written information about any fees, contracts and terms and conditions, relating to the cost of their care or treatment. This was in breach of regulation 19(1) of the Care Quality Commission (Registration) Regulations 2009

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment How the regulation was not being met: • The provider was unable to demonstrate accurate, complete, contemporaneous and legible records of service users in respect of care and treatment provided to the service user and decisions taken in relation to the care and treatment provided. • The registered person did not do all that was reasonably practicable to assess, monitor, manage and mitigate risks to the health and safety of service users. The provider could not demonstrate that they were ensuring patients' health was always monitored in relation to the use of medicines and then being followed up appropriately. • The provider was unable to demonstrate effective systems and processes to ensure the safe management of medicines. • The provider was unable to demonstrate effective systems or processes to assess the risk of, and prevent, detect and control the spread of, infections, including those that are health care associated. • The provider was unable to demonstrate that all staff had the competence to ensure that the assessment, planning and delivery of care and treatment was always carried out in accordance with the Mental Capacity Act 2005. This was in breach of regulation 12(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity	Regulation

This section is primarily information for the provider

Enforcement actions

Diagnostic and screening procedures

Treatment of disease, disorder or injury

Regulation 17 HSCA (RA) Regulations 2014 Good governance

How the regulation was not being met:

- The provider was unable that service policies were comprehensive, up to date and contained relevant information.
- The provider was unable to demonstrate that systems and processes were implemented effectively to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities. This included risk assessments about the health, safety and welfare of people using their service to make required adjustments.
- The provider was unable to demonstrate systems and processes were in place to ensure significant events, complaints and safety alerts were always thoroughly recorded, acted on, analysed and appropriately stored.
- The provider was unable to demonstrate a programme of quality improvement activity to review the effectiveness and appropriateness of the care provided. The provider did not demonstrate clinical audits to monitor the quality of prescribing.

This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulation