Alimentary Innervations Limited

The Functional Gut Clinic

Inspection report

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Overall summary

We carried out an announced comprehensive inspection on 8 August 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 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 providing responsive care in accordance with the relevant regulations.

Are services well-led?

We found that this service was 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.

The Functional Gut Clinic is an independent clinic in the central London, which offers advanced diagnostic and screening procedures in alimentary (relating to nutrition) and gastrointestinal (relating to the stomach and intestine) medicine related healthcare service.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of the services it provides. They provider employs 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.

We spoke with two patients and received 16 patient Care Quality Commission comment cards. All of the comment cards we received were positive about the service. Patients said they were satisfied with the standard of care received and said the staff was approachable, committed and caring.

Our key findings were:

- Staff understood and fulfilled their responsibilities to raise concerns, and to report incidents and near misses.

Summary of findings

- There were arrangements in place to protect children and vulnerable adults from abuse.
- Most risks were generally well managed though improvements were needed in relation to responding to emergency medical situations, business continuity planning, fire evacuation plan (in particular for patients with mobility problems) and the management of legionella.
- The service routinely reviewed the effectiveness and appropriateness of the care it provided. It ensured that care and treatment was delivered according to evidence-based guidelines.
- Consent procedures were in place and these were in line with legal requirements.
- Systems were in place to protect personal information about patients.
- Appointments were available on a pre-bookable basis. The service provided only face to face consultations.
- The practice had excellent facilities and was well equipped to treat patients and meet their needs.
- Staff involved and treated patients with compassion, kindness, dignity and respect.
- Staff had the skills, knowledge and experience to deliver effective care and treatment.
- Staff had received up to date training relevant to their role. Staff appraisals had been completed in a timely manner.
- There was a strong focus on continuous learning and improvement at all levels of the organisation.
- Information about services and how to complain was available.
- The provider was aware of and complied with the requirements of the Duty of Candour.
- There was a clear leadership structure and staff felt supported by management. The service proactively sought feedback from staff and patients, which it acted on.
- There was a clear vision and strategy and staff spoke of an open and supportive culture.

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

- Ensure care and treatment is provided in a safe way to patients.

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

There were areas where the provider **should** make improvements:

- Review and act upon the staff feedback regarding staffing levels of non-clinical staff.
- Develop a formal documented business continuity plan.
- Carry out a Disabled Access Audit or Disability Discrimination Act (DDA) Audit.
- Provide information about a translation service and display in the waiting area.
- Improve access for patients with hearing difficulties.

Professor Steve Field CBE FRCP FFPH FRCGP

Chief Inspector of General Practice

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We have told the provider to take action (see full details of this action in the Requirement Notices at the end of this report).

The impact of our concerns is minor for patients using the service, in terms of the quality and safety of clinical care. The likelihood of this occurring in the future is low once it has been put right.

This was because:

- Most systems and processes were in place to keep patients safe. However, we identified some shortfalls in relation to deal with emergency medical situations, business continuity planning and the management of legionella.
- There was no documented fire evacuation plan which identified how staff could support patients with mobility problems to vacate the premises.
- The service had not carried out a Disabled Access Audit or Disability Discrimination Act (DDA) Audit.
- The service was unable to provide documentary evidence to demonstrate that fixed electrical installation checks of the premises had been carried out.

We also found:

- The service ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions.
- The service maintained appropriate standards of cleanliness and hygiene.
- There was a system for the reporting of significant events and incidents. However, we could not assess its effectiveness as no incidents had been reported.
- There were systems and processes in place to keep patients safe and safeguarded from abuse.
- There were systems in place to protect all patient information and records were stored securely.
- The provider was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.

Are services effective?

We found that this service was providing effective care in accordance with the relevant regulations.

- The clinicians assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards.
- The provider only offered advanced diagnostic and screening procedures to patients who were referred (tertiary referral) by the consultants.
- The service had arrangements in place to coordinate care and share information appropriately. Diagnostic reports were sent back to the consultant for further treatment options.
- The service carried out quality improvement activity including clinical audit to monitor the appropriateness of the care provided.
- There were training and appraisal arrangements in place to ensure staff had the skills, knowledge and competence to deliver effective care and treatment.
- There was an appropriate system for recording and updating patient care and treatment information.

Summary of findings

Are services caring?

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

We found areas where improvements should be made. This was because:

- Translation services were not available for patients who did not have English as a first language.
- The provider did not provide a hearing induction loop or alternative solution for patients with hearing loss.

We also found:

- Systems were in place to ensure that all patient information was stored and kept confidential.
- According to patient feedback, services were delivered with compassion, dignity and respect and they were involved in decisions about their care and treatment.
- We observed a relaxed and friendly atmosphere at the service and members of staff were courteous and helpful to patients.

Are services responsive to people's needs?

We found that this service was providing responsive care in accordance with the relevant regulations.

- The facilities and premises were appropriate for the services being provided.
- There was information available to patients to demonstrate how the service operated.
- Appointments were available on a pre-bookable basis only (tertiary referral by the consultant). The service only offered face to face consultations between 8.30am to 5.30pm Monday to Friday.
- There was a complaints policy which provided information about handling complaints from patients.

Are services well-led?

We found that this service was providing well-led care in accordance with the relevant regulations.

- The provider had a clear vision and strategy.
- There was a clear ethos of patient centred care.
- Governance arrangements were in place and enabled the day to day running of the service. However, some improvements were required to ensure safety and support good governance.
- There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions. However, some improvements were required.
- Service specific policies were available.
- Patient feedback was encouraged and considered in the running of the service.
- Staff we spoke with felt confident to carry out their role and described an open and supportive culture.

The Functional Gut Clinic

Detailed findings

Background to this inspection

Alimentary Innervations Limited offers 1500 to 2000 consultations per year (approximately 5% NHS and 95% private patients). The Functional Gut Clinic is an independent clinic in the central London, which offers advanced diagnostic and screening procedures in alimentary (relating to nutrition) and gastrointestinal (relating to the stomach and intestine) medicine related healthcare service.

The team consists of clinical scientists, clinical physiologists and trainee physiologists. A senior clinical scientist (also a clinical director) and the CQC registered manager are supported by a team of administrative staff.

Services are provided from: The Functional Gut Clinic, 22 Upper Wimpole Street, London, W1G 6NB. We visited this location as part of the inspection on 8 August 2018.

Online services can be accessed from the practice website: www.thefunctionalgutclinic.com.

The service has core opening hours from 8.30am to 5.30pm Monday to Friday.

The service is registered with the Care Quality Commission to provide the regulated activities of diagnostic and screening procedures and treatment of disease, disorder or injury. This service is registered with CQC under the Health and Social Care Act 2008 in respect of the services it provides.

On 8 August 2018, our inspection team was led by a CQC Lead Inspector. The team included a GP specialist advisor.

Pre-inspection information was gathered and reviewed before the inspection. We spoke with the clinical director, the CQC registered manager, the clinicians and administrative staff. We collected written feedback from three members of staff. We looked at records related to patient assessments and the provision of care and treatment. We also reviewed documentation related to the management of the service. We reviewed patient feedback received by the service.

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.

Safety systems and processes

The service had clear systems to keep patients safe and safeguarded from abuse.

- The service had systems to safeguard children and vulnerable adults from abuse. Policies were regularly reviewed and were accessible. The provider did not offer any service to children at the time of our inspection. Whilst the provider did not directly provide services to children there is an expectation that staff working in a health care setting are trained in child safeguarding in line with the intercollegiate guidance. This recommends child safeguarding training and competencies for not only those directly caring for children but also those providing care for their parents or carers.
- All clinicians (clinical scientists, clinical physiologists and trainee physiologists) had received adult and level two child safeguarding training in line with intercollegiate guidance for all staff working in healthcare settings. The provider informed us that the lead clinical scientist was planning to complete level three child safeguarding training.
- The provider understood their responsibilities to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- There was a recruitment policy in place to carry out staff checks, including checks of professional registration where relevant, on recruitment and on an ongoing basis. We found that the records of Disclosure and Barring Service (DBS) checks, qualifications and registration with the appropriate professional body were available on the day of inspection. (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).
- Staff who acted as chaperones were trained for the role and had received a DBS check.
- There was an effective system to manage infection prevention and control. We observed that appropriate standards of cleanliness and hygiene were followed. The provider had carried out an infection control audit.
- The service ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions.
- There were systems for safely managing healthcare waste. There was a contract for the removal of clinical waste and we saw that clinical waste and sharps bins were appropriately managed.
- On registering with the service, a patient's identity was not verified. However, the service only offered diagnostic services to those patients who were referred by the consultants. Patients were able to register with the service by verbally providing a date of birth and address. At each consultation, patients confirmed their identity face to face. They were able to pay by the bank transfer, debit or credit card and cash.
- Specimens were managed safely and transported to a laboratory by courier.
- The provider did not have a formal documented business continuity plan in place. However, they informed us they had considered some plans but did not document them.

Risks to patients

There were some systems to assess, monitor and manage risks to patient safety. However, improvements were required.

- There were arrangements for planning and monitoring the number and mix of staff needed. Staff told us there were usually enough clinical staff to maintain the smooth running of the service and there were always enough staff on duty to keep patients safe. However, the staff we spoke with and written feedback we received on the day of the inspection raised some concerns regarding inappropriate staffing levels of non-clinical staff. The provider informed us they were planning to recruit a new non-clinical staff member in November 2018.
- The staff understood their responsibilities to manage emergencies on the premises and to recognise those in need of urgent medical attention. However, the provider did not have a defibrillator and oxygen available in the service. The service was renting a space in shared premises and staff we spoke with informed us they would request emergency equipment from the neighbouring service or dial 999 to deal with the urgent medical situation. However, the service did not have a formal documented arrangement in place with the

neighbouring service to deal with the urgent medical situation. The service was unable to demonstrate that they had an effective monitoring system to ensure that emergency equipment at the neighbouring practice was fit for purpose.
- There were no emergency medicines available in the service and there was no formal risk assessment as to why they were not required. The provider did not conduct a formal risk assessment to demonstrate that they had considered the possibility that the emergency medicines might be needed, and how to ensure timely administration.
- The staff knew how to identify and manage patients with severe infections, for example, sepsis.
- When there were changes to services the service assessed and monitored the impact on safety.
- The clinicians had a professional indemnity insurance that covered the scope of their practice.

Information to deliver safe care and treatment

- Individual care records were written and managed in a way that kept patients safe. Patient records and consultation notes were stored securely using an electronic record system. Staff used their login details to log into the operating system, which was a secure programme. The clinicians had access to the patient's previous records held by the service. Any paper records were stored securely in the locked room in the locked cabinets.
- The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.
- Risks related to patients' diagnoses and other health and wellbeing risks were recorded in patients' records.
- Diagnostic reports included all of the necessary information.
- The service was registered with the Information Commissioner's Office.

Safe and appropriate use of medicines

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

- The service only had Lidocaine nasal spray (a local anaesthetic used to numb the lining of the mouth and throat before certain medical procedures) in the stock. We noted a qualified doctor had given a written prescribing authorisation to use this medicine in the service. The provider had appropriate protocol in place to use this medicine in the service.
- The medicines we checked were in date and stored securely. The systems for managing and storing medicines minimised risks.
- The service did not prescribe any medicines.

Track record on safety

The service had a track record on safety. However, improvements were required.

- The service conducted safety risk assessments. Safety policies were regularly reviewed.
- An internal fire safety risk assessment had been carried out on 4 April 2018. The service had carried out a fire drill on 17 April 2018 and the electronic fire system was serviced in March 2018. Smoke alarm checks had been carried out weekly.
- The service was located in shared premises on the basement floor. One of the consultation room was on the second floor and the service was able to access a consultation room on the ground floor on the adhoc basis when required. Patients with mobility problems could access the basement floor by using the stairlift. There was no documented fire evacuation plan which identified how staff could support patients with mobility problems to vacate the premises. Push bar had not been installed on the fire exit door.
- The service had not carried out the Disabled Access Audit or Disability Discrimination Act (DDA) Audit.
- The service was unable to provide documentary evidence to demonstrate that fixed electrical installation checks of the premises had been carried out.
- A legionella risk assessment had been carried out on 3 January 2017 and regular water temperature checks had been carried out by the building management who was responsible for managing the premises. (Legionella is a term for a particular bacterium which can contaminate water systems in buildings). This risk assessment had identified a number of risks and the service was unable to demonstrate that they had an effective monitoring system to ensure that remedial actions had been undertaken.

Are services safe?

- The practice had a variety of other risk assessments to monitor the safety of the premises such as control of substances hazardous to health (COSHH), gas safety checks and infection control risk assessment.
- All electrical and clinical equipment was checked and calibrated to ensure it was safe to use and was in good working order.

Lessons learned and improvements made

- There was an incident reporting policy for staff to follow and there were procedures in place for the reporting of incidents and significant events. However, we could not assess its effectiveness as no incidents had been reported.
- The service had signed up to receive patient and medicine safety alerts. They provided examples of alerts they had received but there were no examples of alerts being acted on as none had been relevant.
- The registered manager demonstrated an understanding of which incidents were notifiable under the duty of candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment).

When there were unexpected or unintended safety incidents:

- The service gave affected people reasonable support, truthful information and a verbal and written apology
- They kept written records of verbal interactions as well as written correspondence.

Are services effective?

(for example, treatment is effective)

Our findings

We found that this service was providing effective care in accordance with the relevant regulations.

Effective needs assessment, care and treatment

The service had systems to keep the clinicians up to date with relevant and current evidence-based guidance and standards such as the National Institute for Health and Care Excellence (NICE) and the British Society of Gastroenterology (BSG) best practice guidelines. The senior clinical scientist was involved in producing guidelines and pathways with the Association of Gastrointestinal Physiologists (AGIP).

- The provider had specialised in offering advanced diagnostic and screening procedures in alimentary (relating to nutrition) and gastrointestinal (relating to the stomach and intestine) medicine related healthcare service. On average they offered 1500 to 2000 consultations per year (approximately 5% NHS and 95% private patients).
- The service offered preoperative assessment and post operative care for surgical procedures in gastrointestinal surgery. The surgical procedures were not offered at the service. The surgical procedures were offered at other registered establishments under practising privileges.
- The provider only offered diagnostic services to patients who were referred (tertiary referral) by the consultants.
- The service used a comprehensive assessment process to ensure greater accuracy in the diagnosis process. The assessments were tailored according to information on each patient and included their clinical needs and their mental and physical wellbeing. The service carried out advanced medical investigations, analysed the results and developed a diagnostic report. The diagnostic report was sent back to the consultant for further treatment options.
- The service ensured that all patients were seen face to face for their consultation.
- All patients completed a medical questionnaire at their first visit which included information about their past medical history, personal details, date of birth and NHS GP details (plus consent to update NHS GP of all consultations details).
- We reviewed examples of medical records which demonstrated that patients' needs were fully assessed and they received care and treatment supported by clear clinical pathways and protocols.

Monitoring care and treatment

We saw the service had an effective system to assess and monitor the quality and appropriateness of the care provided.

- The clinicians were not responsible for managing and monitoring patients' long-term health conditions. Diagnostic results were sent back to the consultants and they would prescribe or adjust further treatment. Results were shared with patients NHS GP with their consent.
- The clinicians had access to all previous notes. Patients' notes and results were monitored to ensure service was delivered in line with current standards and guidance supported by clear clinical pathways and protocols.
- The clinicians advised patients what to do if their condition got worse and where to seek further help and support. Patients were given a business card with a clinician's mobile telephone number and they were able to contact the clinician to discuss any concerns.
- We found the service was following up on pathology results and had an effective monitoring system in place to ensure that all abnormal results were managed in a timely manner and saved in the patient's records.

The provider had carried out quality improvement activity and routinely reviewed the effectiveness and appropriateness of the care and treatment provided.

- The service had carried out monthly peer reviews of clinical reports of each clinician to monitor the quality of reports produced.
- Consent audits were carried out every four months to identify patients who had consent forms missing in their electronic patient records or to ensure that consent forms were appropriately completed.
- The service had carried out monthly audits to identify why patients had cancelled or missed the pre-book appointments to understand the reasons and improve their service.
- The service had undertaken monthly audits to monitor referral action timescales.
- The service had carried out six monthly peer reviews of referring clinician's response from reports.

Are services effective?

(for example, treatment is effective)

- The service had carried out monthly audits of non-invoiced appointments.

Patient feedback was sought via questionnaires and surveys on the support and care provided. This was highly positive about the quality of service patients received.

Effective staffing

Staff had the skills, knowledge and experience to carry out their roles.

- The service had employed clinical scientists, clinical physiologists and trainee physiologists. A senior clinical scientist (also a clinical director) and the CQC registered manager were supported by a team of administrative staff to deal with telephone, email and face to face queries and book appointments.
- The clinicians were registered with the professional organisations including the Health and Care Professions Council (HPCP), the Association for Group and Individual Psychotherapy (AGIP) and the British Society of Gastroenterology (BSG).
- The service had kept the evidence of clinicians' professional qualification in their staff files.
- All staff had received an appraisal within the last 12 months and some staff had started recently and were not due an appraisal yet. Staff we spoke with informed us they received regular coaching, mentoring and support through regular meetings.
- All staff had received ongoing training relevant to their role. This included: safeguarding children and adults, infection control, basic life support, health and safety, equality and diversity and fire safety training.

Coordinating patient care and information sharing

- Patients received coordinated and person-centred care.
- Diagnostic reports were sent back to the consultant so they could decide if a patient needed further examination or treatment.
- When a patient contacted the service, they were asked if the details of their consultation could be shared with their NHS GP. If the patient did not agree to the service sharing information with their GP, then in case of an emergency the provider discussed this again with the patient to seek their consent.
- Correspondence was shared with external professionals in a way that ensured data was protected. Information required passwords in order to access any data shared with external providers.

Supporting patients to live healthier lives

The clinicians were consistent and proactive in helping patients to live healthier lives.

- They encouraged and supported patients to be involved in monitoring and managing their health.
- They discussed changes to care or treatment with patients as necessary.
- Patients had access to appropriate health assessments and checks.

Consent to care and treatment

- The clinicians understood and sought patients' consent to care and treatment in line with legislation and guidance. If a patient's mental capacity to consent to care or treatment was unclear we were told the clinician would assess the patient's capacity and record the outcome of the assessment.
- The service had a consent policy in place and the clinicians had received training on consent.
- The clinicians demonstrated a clear understanding of the Gillick competency test. (These are used to help assess whether a child under the age of 16 has the maturity to make their own decisions and to understand the implications of those decisions).
- We were told that any treatment including fees was fully explained to the patient prior to the procedure and that people then made informed decisions about their care.

Are services caring?

Our findings

We found that this service was providing caring services in accordance with the relevant regulations. However, we found areas where improvements should be made.

Kindness, respect and compassion

- The staff we spoke with was aware of their responsibility to respect people's diversity and human rights.
- Staff understood patients' personal, cultural, social and religious needs.
- The service gave patients timely support and information.
- We obtained the views of patients who used the service. We spoke with two patients and received 16 patient Care Quality Commission comment cards. All of the comment cards we received were positive about the service.
- Patients said they felt the provider offered an excellent service and the staff was helpful, caring and treated them with dignity and respect. They told us they were satisfied with the care provided by the provider and said their dignity and privacy was respected. They said staff responded compassionately when they needed help and provided support when required.
- We saw that staff treated patients respectfully and politely at the reception desk and over the telephone.

Involvement in decisions about care and treatment

- The service gave patients clear information to help them make informed choices including details of the scope of services offered and information on fees.
- We saw that diagnostic and screening procedures were personalised and patient specific which indicated patient were involved in decisions about care and treatment.
- Patients told us they felt listened to and supported by the clinician and had sufficient time during consultations to make an informed decision about the choice of screening options available to them.
- Feedback suggested that patients felt diagnosis and screening options were explained clearly to them.
- We found that interpretation services were not available for patients who did not have English as a first language.
- The service did not provide a hearing induction loop or alternative solution for those patients who were hard of hearing.

Privacy and Dignity

The service respected and promoted patients' privacy and dignity.

- Staff recognised the importance of patients' dignity and respect.
- The service complied with the Data Protection Act 1998.
- The service had a confidentiality policy in place and systems were in place to ensure that all patient information was stored and kept confidential. Staff were mindful and adherent to the provider's confidentiality policy when discussing patients' needs.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- We noted that consultation room doors were closed during consultations and that conversations taking place in these rooms could not be overheard.
- The service had arrangements in place to provide a chaperone to patients who needed one during consultations.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

We found that this service was providing responsive care in accordance with the relevant regulations.

Responding to and meeting people's needs

- Patient's individual needs and preferences were central to the planning and delivery of tailored services. Services were flexible, provided choice and ensured continuity of care.
- The provider offered diagnostic and screening procedures to anyone who was referred (tertiary referral) by the consultant and paid the appropriate fee, and did not discriminate against anyone.
- The facilities and premises were appropriate for the services delivered.
- There was a patients' leaflet which included arrangements for dealing with complaints, information regarding access to the service, consultation and treatment fees, terms and conditions, and a cancellation policy.
- The service website was well designed, clear and simple to use featuring regularly updated information.

Timely access to the service

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

- Patients had timely access to initial assessment, test results, diagnosis and screening. Patients were offered various appointment dates to help them arrange for suitable times to attend.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- The appointment system was easy to use. Appointments were available on a pre-bookable basis only (tertiary referral by the consultant). The service only offered face to face consultations.
- Consultations were available between 8.30am to 5.30pm Monday to Friday.
- Patients could access the service in a timely way by making their appointment over the telephone or by email.
- This service was not an emergency service. Patients who had a medical emergency were advised to ask for immediate medical help via 999 or if more appropriate to contact their own GP or NHS 111.
- The patient feedback we received confirmed they had flexibility and choice to arrange appointments in line with other commitments.

Listening and learning from concerns and complaints

The service had a system in place for handling complaints and concerns.

- The service had a complaints policy and there were procedures in place for handling complaints. The policy contained appropriate timescales for dealing with the complaint. There was a designated responsible person to handle all complaints.
- The complaints policy included information of the complainant's right to escalate the complaint to the Centre for Effective Dispute Resolution (CEDR) if dissatisfied with the response.
- Information about how to make a complaint was available on the service's website and on the patient's leaflet.
- We looked at three complaints received in the last 12 months and found that all complaints had been addressed in a timely manner and patients received a satisfactory response. There was evidence that the service had provided an apology and used the information provided by the patient to review the service. For example, the provider informed us they had reviewed their information governance arrangements and organised an information governance training to improve staff skills.

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 providing well-led care in accordance with the relevant regulations. However, we found areas where improvements should be made.

Leadership capacity and capability;

Leaders had the capacity and skills to deliver high-quality care.

- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges to run the service.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.

Vision and strategy

- The provider had a clear vision to provide a high-quality and effective healthcare service.
- The service's stated aims and objectives were to provide the highest professional and ethical standards which meet and exceeds patients' expectations and to encourage innovation, ambition, enterprise and continuous improvement. This included working in partnership with staff and maintaining a highly motivated skilled workforce, in order to support each other in achieving patient expectations.

Culture

- The service had an open and transparent culture. We were told that if there were unexpected or unintended safety incidents, the service would give affected patients reasonable support, truthful information and a verbal and written apology.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour. (The duty of candour is a set of specific legal requirements that providers of services must follow when things go wrong with care and treatment).
- The service focused on the needs of patients.
- 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 positive relationships between staff and the leaders.
- There were processes for providing all staff with the development they need.

Governance arrangements

There were clear responsibilities, roles and systems of accountability to support good governance and management.

- The service had a governance framework which supported the delivery of the strategy and good quality care. However, some improvements were required to ensure safety and support good governance.
- Staff were clear on their roles and accountabilities including in respect of safeguarding and health and safety.
- There was a range of service specific policies which were accessible.

Managing risks, issues and performance

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The service identified, assessed and managed some clinical and environmental risks related to the service provided.
- Service leaders had oversight of safety alerts, incidents, and complaints.
- The service had processes to manage current and future performance. Performance of employed clinical staff could be demonstrated through the audit of their consultations and diagnostic reports. Quality and operational information was used to ensure and improve performance.
- The service used information technology systems to monitor and improve the quality of care.
- There were regular reviews of service performance and progress towards strategic goals. Service leaders closely reviewed the data and performance of the service and actions were taken to address concerns when they arose. This ensured a comprehensive understanding of the overall performance of the service was maintained.
- The service had plans in place and had trained staff for major incidents. However, the service did not have a formal documented business continuity plan in place.

Appropriate and accurate information

The service acted on the appropriate and accurate information.

- Patient assessments, diagnostic and screening reports and consultation notes were recorded on a secure

Are services well-led?

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

electronic system. We reviewed anonymised assessment reports where a diagnosis was made. We found that the assessments included clear information and recommendations. The clinicians responsible for monitoring patients' care were able to access notes from all the previous consultations.
- Care and treatment records were complete, legible and accurate, and securely kept.
- The service was registered with the Information Commissioners Office (ICO).

Engagement with patients, the public, staff and external partners

The service encouraged and valued feedback from patients and staff.

- Comments and feedback were encouraged and reviewed. The service had carried out a patients' survey in April 2018. The results were highly positive about the quality of service patients received and high satisfaction levels. The provider had received 21 responses and achieved 4.8 points out of five available points.
- Staff meetings were held regularly which provided an opportunity for staff to learn about the performance of the service.
- The service was transparent, collaborative and open with stakeholders about performance.
- The provider had a whistleblowing policy in place. (A whistle-blower is someone who raises concerns about practice or staff within the organisation.)

Continuous improvement and innovation

- The service consistently sought ways to improve. There was a focus on continuous learning and improvement at all levels within the service. All staff were encouraged to identify opportunities to improve the service delivered.
- The clinicians were engaged in continuous professional development.
- The service had developed and shared videos on their website to demonstrate how to use home testing equipment taken home by the patients.
- The service had renewed accreditation with United Kingdom Accreditation Service (UKAS) for the next four years after the successful completion of the comprehensive assessment.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment **How the regulation was not being met:** The provider had not done all that was reasonably practicable to mitigate risks to the health and safety of service users receiving care and treatment. In particular: There was no emergency equipment available in the service. The provider was relying on the neighbouring service but they did not have a formal documented arrangement in place with the neighbouring service to deal with the urgent medical situation. The service was unable to assure that emergency equipment at the neighbouring practice was fit for purpose. There were no emergency medicines available in the service and there was no formal documented risk assessment as to why they were not required. There was no documented fire evacuation plan. The provider did not identify how staff could support patients with mobility problems to vacate the premises. The service was unable to demonstrate whether remedial actions had been undertaken to address a number of risks identified during previous legionella risk assessment. The service was unable to provide documentary evidence to demonstrate that fixed electrical installation checks of the premises had been carried out. This was in breach of regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.