

The Natural Doctor

Inspection report

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Date of inspection visit: 10 July 2019
Date of publication: 19/09/2019

This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location

Requires improvement 

Are services safe?

Requires improvement 

Are services effective?

Requires improvement 

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Requires improvement 

Overall summary

This service is rated as Requires improvement **overall.**

The key questions are rated as:

Are services safe? – Requires improvement

Are services effective? – Requires improvement

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Requires improvement

We carried out an announced comprehensive inspection at The Natural Doctor as part of our inspection programme. This was the first inspection undertaken at this service.

The Natural Doctor is an independent clinic in central London, which provides a range of bespoke healthcare service to adults and specialises in individualised bioidentical hormone replacement therapy and functional medicine.

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 and of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Natural Doctor provides a range of services, for example, breast thermography, breast health consultations, natural hair restoration, natural sexual health products, natural fertility treatment and PULS (Protein Unstable Lesion Signature) cardiovascular risk assessment, which are not within CQC scope of registration. Therefore, we did not inspect or report on these services.

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

Fourteen people provided feedback about the service, which was positive about the care and treatment offered by the service. They were satisfied with the standard of care received and thought the doctor was approachable, committed and caring. They said the staff were helpful and treated them with dignity and respect.

Our key findings were:

- The service had specialised in individualised bioidentical hormone replacement therapy and functional medicine for adults. Patients were treated with unlicensed compounded medicines.
- Risks to patients were assessed and well managed in some areas, with the exception of those relating to fire drills, emergency medicines, emergency equipment and the management of legionella.
- The clinical equipment was not calibrated and maintained according to manufacturers' instructions to ensure it was safe to use and was in good working order.
- The service was unable to provide documentary evidence to demonstrate that all staff had completed training relevant to their role.
- There was limited evidence of overall quality improvement activity. However, individual patients were monitored to review the effectiveness and appropriateness of the care provided.
- Consultations were comprehensive and undertaken in a professional manner.
- Consent procedures were in place and these were in line with legal requirements.
- Appointments were available on a pre-bookable basis. The service provided consultations face to face, via telephone and video calls. All initial consultations were face to face.
- Staff involved and treated patients with compassion, kindness, dignity and respect.
- 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.

The areas where the provider **must** make improvements as they are in breach of regulations are:

- 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 and professional development necessary to enable them to carry out the duties.

Overall summary

(Please see the specific details on action required at the end of this report).

The areas where the provider **should** make improvements are:

- Only supply unlicensed medicines against valid special clinical needs of an individual patient where there is no suitable licensed medicine available and with the full informed consent of the patient including making them aware of any possible long term effects.
- Make access and information available for patients who do not speak English.

- Improve access for patients with hearing difficulties.
- Share information that a toilet on the premises is not accessible for patients with mobility issues.
- Follow their own policy on including in all responses to complaints the complainant's right to escalate the complaint if dissatisfied with the response.

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a GP specialist adviser.

Background to The Natural Doctor

The Natural Doctor is an independent clinic in central London, which provides a range of bespoke healthcare service to adults and specialises in individualised bioidentical hormone replacement therapy and functional medicine. On average they offer 90 doctor consultations per month.

The Natural Doctor Limited is a private limited company and the provider of this independent healthcare service. The service is renting a consultation room, a small scan room and an office space on the ground floor. The service is run by a doctor. The service employs a practice manager who is supported by four administrative staff. The doctor is performing duties as a medical director and responsible for the management and day to day running of the service.

Services are provided from: 69 Harley Street, London, W1G 8QW. We visited this location as part of the inspection on 10 July 2019.

Online services can be accessed from the practice website: www.thenaturaldoctor.org.

The service has core opening hours from 9am to 5pm Monday to Friday. The service offers services for adults only. Consultations are available between 9am to 5pm on Monday, Wednesday and Thursday. Appointments for the scan are available between 9am and 5pm 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.

How we inspected this service

Pre-inspection information was gathered and reviewed before the inspection. We spoke with the doctor, a practice manager and an administrative 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?

We rated safe as Requires improvement because:

- The service had not always ensured that clinical equipment was calibrated and maintained according to manufacturers' instructions to ensure it was safe to use and was in good working order.
- The service was unable to demonstrate they had adequate health and safety arrangements in place to ensure the management of legionella in the premises.
- Risks to patients were not assessed and well managed in relation to fire drills, emergency medicines, emergency equipment, safeguarding children policy, child safeguarding training and chaperone training.
- A spill kit was not available.

Safety systems and processes

The service had some systems to keep people safe and safeguarded from abuse. However, improvements were required.

- The service was renting space in shared premises and the host was responsible for managing the premises. The service conducted safety risk assessments. Staff received safety information from the service as part of their induction. The service had appropriate safety policies, which were regularly reviewed and communicated to staff. They outlined clearly who to go to for further guidance. However, we noted the service had not developed a documented safeguarding children policy, which could be required if they were dealing with a child safeguarding concern.
- The service did not treat children (under 18 years old) at the time of our inspection. Whilst the provider did not directly provide clinical services for patients under 18 there is an expectation that staff working in a health care setting are trained in child safeguarding in line with the intercollegiate guidance 'Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff'. 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.
- No staff had received any formal child safeguarding training relevant to their role in line with intercollegiate guidance for all staff working in healthcare settings. All staff had received adult safeguarding training relevant to

their role. The doctor was the safeguarding lead and the service was unable to provide documentary evidence that the doctor had completed any formal safeguarding children training appropriate to their role.

- The service had systems to safeguard vulnerable adults from abuse. Staff we spoke with understood their responsibilities to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. 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).
- Staff who acted as chaperones were not trained for the role. However, they had received a DBS check.
- There was an effective system to manage infection prevention and control. The service had carried out an infection control audit. We noted a spill kit was not available.
- The service had not always ensured that equipment was safe, and that equipment was maintained according to manufacturers' instructions. For example, the service could not show a blood pressure monitor and a weighing scale had been checked and calibrated according to manufacturers' instructions to ensure it was safe to use and was in good working order.
- The service had a business continuity plan in place.
- On registering with the service, a patient's identity was verified. Patients were able to register with the service by providing a photographic identity, date of birth and address. At each consultation, patients confirmed their identity face to face. They were able to pay by debit or credit card and cash.
- Specimens were not handled at the service and the patients were advised to visit the local laboratory to use pathology services.

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.

Are services safe?

- There was an effective induction system for agency staff tailored to their role.
- The doctor understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. However, the service did not have a defibrillator and oxygen available in the service. The service was renting a space (on the ground floor) in shared premises and staff we spoke with informed us they would request oxygen from the neighbouring service on the first floor and a defibrillator from the reception on the ground floor to deal with the urgent medical situation. The service informed us they had a formal arrangement in place with the neighbouring service and the host to deal with the urgent medical situation. The service informed us they carried out regular checks every six months to ensure that emergency equipment at the neighbouring practice and at the reception was fit for purpose. However, the service had no documentary evidence of having risk assessed whether they would have timely access to suitable emergency equipment to deal with an urgent medical situation.
- The doctor knew how to identify and manage patients with severe infections, for example sepsis.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place to cover all potential liabilities.

Information to deliver safe care and treatment

Staff had the information they needed to deliver safe care and treatment to patients.

- Individual care records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way. Any paper records were stored securely in the locked cabinets. The doctor had access to the patient's previous records held by the service. The service was in the process of scanning and saving all paper records on the electronic record system.
- Patient records were stored securely on a cloud-based server using an electronic record system. Staff used their computing device to log into the operating system, which was a secure programme.
- Risks related to patients' diagnoses and other health and wellbeing risks were recorded in patients' records.

- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.

Safe and appropriate use of medicines

The service had systems for appropriate and safe handling of medicines. However, some improvements were required.

- The systems and arrangements for managing medicines, including medical gases, emergency medicines and equipment minimised risks.
- Some emergency medicines were available at the service. The doctor informed us they had considered which emergency medicines were required and decided to keep only some emergency medicines. However, the service was unable to provide a formal documented risk assessment to demonstrate that they had considered the possibility that the other emergency medicines might be needed, and how to ensure timely administration.
- At this service, we found that patients were treated with unlicensed medicines. (Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy. The Medicine and Healthcare products Regulatory Agency (MHRA) guidance states that unlicensed medicines may only be supplied against valid special clinical needs of an individual patient. The General Medical Council's prescribing guidance specifies that unlicensed medicines may be necessary where there is no suitable licensed medicine).
- The doctor prescribed functional medicines and compounded medicines. (Compounded medicines are made based on a practitioner's prescription in which individual ingredients are mixed together in the exact strength and dosage form required to meet a patient's individual needs).
- The service mostly used a pharmacy based in Athens that were registered with an appropriate regulator in Greece (which is part of the European Union). They turned powdered bioidentical hormones into medical preparations such as creams, gels, lozenges and pessaries.

Are services safe?

- Once the doctor prescribed the medicine and dosage of choice, relevant instructions were given to the patient regarding when and how to take the medicine, the purpose of the medicine and any likely side effects and what they should do if they became unwell.
- The private prescriptions were hand written or printed on the letterhead which included a company name and other necessary information. These paper prescriptions were prescribed and signed by the doctor. All paper prescriptions were scanned and saved in the patient's record. There was a record of what was prescribed in the patient consultation notes.
- The service had a repeat prescribing policy and repeat prescriptions were issued for the patients whose conditions were stable and using the medicines for some time. All patients were advised to attend a follow up appointment with the service, without which the doctors would not prescribe further medicines.
- The service did not prescribe any controlled drugs or any high risk medicines which required regular monitoring.
- We noted that the safety of electrical portable equipment was assessed at the premises to ensure they were safe to use.
- An asbestos survey was carried out on 18 November 2011. The survey had found traces of asbestos material on the second floor. However, the service was renting a consultation room, a small scan room and an office space on the ground floor. Staff we spoke with was not aware if any action had been taken by the host to carry out asbestos removal work from the second floor of the listed building.
- The legionella (a bacterium which can contaminate water systems in buildings) risk assessment was not carried out. The host was responsible to carry out water temperature checks. We noted water temperatures were recorded outside the recommended ranges on a number of occasions, but the appropriate remedial action had not been taken to address the issues.

Track record on safety and incidents

The service had a good safety record in some areas. However, improvements were required.

- The service was renting space in shared premises and the host was responsible for managing the premises.
- There was an up to date fire risk assessment carried out by an external contractor on 10 March 2017. The fire risk assessment had identified a number of risk areas and recommended actions to ensure fire safety in the premises. The service informed us that remedial actions had been taken to address the risks identified in the fire risk assessment. However, there was no documentary evidence available to demonstrate that regular fire drills were carried out. The service informed us a day after the inspection, the host had planned to carry out a fire drill in August 2019. The service was planning to carry out a new fire safety risk assessment in August 2019.
- The fire system and fire extinguishers were serviced regularly, and smoke alarm checks had been carried out.
- Electrical installation condition inspection had been carried out in July 2018.

Lessons learned and improvements made

The service learned and made improvements when things went wrong.

- The doctor understood their duty to raise concerns and report incidents and near misses. 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 doctor 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).
- The service had signed up to receive patient and medicine safety alerts. The doctor provided examples of alerts they had received but there were no examples of alerts being acted on as none had been relevant.

When there were unexpected or unintended complaints:

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

Are services effective?

We rated effective as Requires improvement because:

- There was limited evidence of overall quality improvement activity. However, individual patients were monitored to review the effectiveness and appropriateness of the care provided.
- The service was unable to provide documentary evidence to demonstrate that all staff had received ongoing training relevant to their role.

Effective needs assessment, care and treatment

The service had assessed needs and delivered care and treatment in line with their internal protocols.

- The service informed us that each patient had been assessed and monitored individually with regular clinical follow-up reviews to determine the effectiveness and safety of the bioidentical hormone replacement therapy (BHRT) treatment provided.
- The service ensured that all patients were seen face to face for their initial consultation and in person at least annually thereafter.
- We reviewed nine examples of medical records which demonstrated that the service used a comprehensive assessment process including full life history accounts and necessary examinations such as blood tests or scans 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 outcomes of each assessment were clearly recorded and presented with explanations to make their meaning clear. This information was used to build female and male patients hormone profile and included a discussion on the treatment options. Follow-up assessments included documentation of the effectiveness of treatment plan (which included symptom relief and normalisation of specific hormones) as well as notation of any side effects. Changes to the treatment plan were discussed if appropriate to ensure the patient's needs were met and to allow the opportunity to make any improvements to the quality of care.
- We saw no evidence of discrimination when making care and treatment decisions.
- Staff assessed and managed patients' pain where appropriate.

Monitoring care and treatment

There was limited evidence of overall quality improvement activity. However, individual patients were monitored to review the effectiveness and appropriateness of the care provided.

- The service had arrangements to review and monitor the treatment of patients on long-term medicines.
- Patients' health was monitored to ensure medicines were being used safely and followed up on appropriately. Patients were required to attend a periodic check with the service, without which the doctor would not prescribe further medicines.
- The service involved patients in regular reviews of their medicines. After the initial face to face consultation (45 minutes), the service offered a follow up consultation (30 minutes) two weeks later to discuss the scan or blood test results.
- The service offered regular progress reviews after three months and/ or six months to monitor and adjust the treatment according to a patient's symptoms and needs. The doctor had access to all previous notes.
- The service used information about care and treatment to make improvements. For example, the service informed us they employed a five-stage clinical audit approach to assess, review and monitor the quality and appropriateness of the care provided. All patients were advised to attend a follow-up appointment to review their symptoms, including bespoke 29-symptom questionnaire and if necessary to carry out blood tests again to assess changes in marker hormones. This provided the relevant information needed to make a clinical judgement and make any changes in the treatment in order to improve effectiveness or reduce any adverse effects or other challenges the patient might face. The service informed us they judged clinical effectiveness on the basis of both quantitative markers (normalisation of hormone levels) and qualitative ones (patient symptom reports, the patient's perceived health and vitality and the patient's general satisfaction with the integrated approach).
- The service informed us they carried out regular patients' satisfaction surveys to measure the effectiveness of the care provided.
- The doctor advised patients what to do if their condition got worse and where to seek further help and support.

Are services effective?

There was limited evidence of overall quality improvement activity. For example,

- The provider had not carried out any clinical audits to assess and monitor the overall clinical quality and appropriateness of the care provided.
- The provider had not carried out clinical trials at the service to demonstrate the safety and effectiveness of the BHRT treatment provided. However, they had considered and reviewed relevant trials published by other clinicians or researchers.
- There were no prescribing audits to monitor the individual prescribing decisions to monitor the quality of the prescriptions issued, but individual patients on prescribed medicines were monitored to identify the appropriateness of their medicines. Overall clinical outcomes for patients were monitored.

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.

Effective staffing

Most staff had the skills, knowledge and experience to carry out their roles. However, improvements were required.

- The service was run by a doctor (who was also the medical director and CQC registered manager). The service employed a practice manager who was supported by four administrative staff.
- The doctor was registered with the General Medical Council (GMC) the medical professionals' regulatory body with a licence to practice and was also on the GP register. The doctor was a member of the Royal College of Physicians (MRCP).
- The doctor was registered with the Independent Doctors Federation (IDF) the independent medical practitioner organisation in Great Britain. (IDF is recognised as the nationwide voice of independent doctors in all matters relating to private medicine, their education and revalidation).
- The doctor had a responsible officer. (All doctors working in the United Kingdom are required to have a responsible officer in place and required to follow a process of appraisal and revalidation to ensure their fitness to the clinic). The doctor was following the required appraisal and revalidation processes.

- The doctor had received an appraisal in March 2019.
- The doctor had attended role-specific training and demonstrated proof of their ongoing professional development.
- The service had an induction programme for all newly appointed staff.
- Staff had received specific internal training to operate an infrared camera, which was used to carry out breast thermography scans. All scans were carried out by trained female administrative staff.
- All staff had received appraisal within the last year.
- The service was unable to provide documentary evidence to demonstrate that all staff had received ongoing training relevant to their role. Not all staff had received training that included: safeguarding children (all staff), safeguarding adults (two administrative staff), infection control (the doctor and two administrative staff), basic life support (two administrative staff), health and safety (the doctor and two administrative staff), infection control (the doctor and two administrative staff), equality and diversity (the doctor and four administrative staff), chaperone (four administrative staff), information governance (the doctor and four administrative staff) and fire safety training (the doctor and four administrative staff had not received training).

Coordinating patient care and information sharing

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

- Patients received coordinated and person-centred care.
- Before providing treatment, the doctor at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history.
- If a patient needed further examination they were directed to an appropriate agency, their own GP or to their nearest A&E department as well as referral letters to private consultants.
- 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. 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.

Are services effective?

- 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

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

- Where appropriate, staff gave people advice so they could self-care.
- Risk factors were identified and highlighted to patients.
- Where patients needs could not be met by the service, staff redirected them to the appropriate service for their needs.
- The service had a range of information available on their website. For example, there was information available regarding the use of alternative medicines, hair restoration, breast health, vitamin D deficiency, fatigue and a number of blogs discussing women's and men's health issues.
- Nutritional supplements had been recommended by the doctor to promote a healthy life style and could be ordered from the professional healthcare websites and did not require a formal prescription.

Consent to care and treatment

The service obtained consent to care and treatment in line with legislation and guidance .

- The doctor understood the requirements of legislation and guidance when considering consent and decision making.
- The doctor supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.
- The service monitored the process of seeking consent appropriately.
- The doctor informed us that information regarding the use of medicine outside of its licence was provided, the risks explained to the patient and documented during the consultations. We saw evidence of consent by the patient to acknowledge and accept that they were receiving medicine for use outside of its licence. However, there was no information available on the service's website which informed people about the risks associated with the use of an unlicensed medicine.
- 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.
- There was information on the service's website with regards to how the service worked and what costs applied including a set of frequently asked questions for further supporting information. The website had details on how the patient could contact them with any enquiries.

Are services caring?

We rated caring as Good because:

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- 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.
- As part of our inspection, we also asked for the Care Quality Commission (CQC) comment cards to be completed by patients prior to our inspection. All of the eight patient CQC comment cards we received were positive about the service experienced.
- Six online feedbacks we received (via the CQC website) from patients were positive about the way staff treat people. We did not speak to patients directly on the day of the inspection.
- We reviewed patient feedback available online (social media) which was positive.

Involvement in decisions about care and treatment

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

- Feedback from patients reflected 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.

- The service gave patients clear information to help them make informed choices including information on the service's website. The information included details of the scope of services offered and information on fees.
- We saw that treatment plans were personalised and patient specific which indicated patient were involved in decisions about care and treatment.
- Information leaflets were available, to help patients be involved in decisions about their care.
- Interpretation services were not available for patients who did not have English as a first language. Staff informed us translation services were rarely required as patients usually attended with an English speaking relative or friend.
- The service did not provide a hearing induction loop.

Privacy and Dignity

The service respected patients' privacy and dignity.

- Staff recognised the importance of people's dignity and respect.
- Staff knew that if patients wanted to discuss sensitive issues or appeared distressed they could offer them a private room to discuss their needs.
- The service had a confidentiality policy in place and systems were in place to ensure that all patient information was stored and kept confidential.

Are services responsive to people's needs?

We rated responsive as Good because:

Responding to and meeting people's needs

The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.

- Patients' individual needs and preferences were central to the planning and delivery of tailored services. Services were flexible, provided choice and ensured continuity of care, for example, telephone or Skype consultations were available for patients that chose to use this service.
- They provided services to patients with an ethos of providing individualised care and treatment, considering and respecting the wishes of its patients.
- The service offered consultations to anyone who requested and paid the appropriate fee, and did not discriminate against anyone.
- There was a patients' information pack which included leaflets regarding various consultations services and health products offered at the service.
- The service website was well designed, clear and simple to use featuring regularly updated information regarding access to the service, consultation and treatment fees, complaints, terms and conditions, and cancellation policy.
- The facilities and premises were appropriate for the services delivered. The premises were accessible for patients with mobility issues. A toilet was available for the patients on the ground floor. However, it was not accessible for patients with mobility issues. The clinic was situated in a listed building and it was not feasible to make structural changes in the premises. The patients were signposted to other similar services with disabled toilet access. However, this information was not available on the service's website.
- The practice made reasonable adjustments when patients found it hard to access services. There were two steps going up to the premises main entrance. They had a portable ramp that could be used to wheelchair or pushchairs users access the premises.

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 the initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Feedback showed patients were able to access care and treatment within an acceptable timescale for their needs.
- The service aimed to provide an appointment for their patients to undertake an assessment as soon as possible and informed us that assessments were usually undertaken within one to two weeks of any request. Patients were offered various appointment dates to help them arrange for suitable times to attend.
- The service informed us that the initial consultation appointment was only offered face to face for 45 minutes. Follow up consultation appointments (30 minutes) were usually offered after two weeks.
- The clinic and telephone lines were open between 9am and 5pm Monday to Friday. Appointments were available on a pre-bookable basis. The service offered consultations face to face, via telephone and video calls. Consultations were available between 9am to 5pm on Monday, Wednesday and Thursday. Appointments for scan were available between 9am and 5pm Monday to Friday.

Listening and learning from concerns and complaints

The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.

- Information about how to make a complaint or raise concerns was available on the service's website. Staff treated patients who made complaints compassionately.
- There was a designated responsible person to handle all complaints.
- The service had complaint policy and procedures in place. The policy contained appropriate timescales for dealing with the complaint. The complaints policy included information of the complainant's right to escalate the complaint to the external clinical governance manager if dissatisfied with the response. However, it did not include complainant's right to escalate the complaint to the Independent Doctors Federation (IDF) and Independent Healthcare Sector Complaints Adjudication Service (ISCAS) if dissatisfied with the response.

Are services responsive to people's needs?

- The service had received three complaints in the last 12 months. We noted complaints had been addressed in a professional and timely manner. However, complaint responses did not inform patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service learned lessons from individual concerns, complaints and from analysis of trends. It acted as a result to improve the quality of care. For example, there was evidence that the service had provided an apology and refunded the consultation charges. The service had organised an internal workshop to discuss and improve customer service skills.

Are services well-led?

We rated well-led as Requires improvement because:

- There was limited evidence of clinical governance to ensure effective monitoring and assessment of the overall quality of the service.
- There were some processes in place for managing risks, issues and performance. However, improvements were required.

Leadership capacity and capability

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

- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.
- The doctor, who was also a medical director and a UK based GMC registered doctor, had overall responsibility for any medical issues arising.

Vision and strategy

The service had a clear vision and credible strategy to deliver high quality care and promote good outcomes for patients.

- The service 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 to offer the patient-centred healthcare service, integrating the highest quality products with the latest proven ethical techniques and safest protocols.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.

Culture

The service had a culture of high-quality sustainable care. However, some improvements were required.

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients.

- The doctor and practice manager acted on behaviour and performance inconsistent with the vision and values.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing all staff with the development they need. However, the service was unable to provide documentary evidence that all staff had completed training relevant to their role. All staff received regular annual appraisals in the last year.
- The service actively promoted equality and diversity. It identified and addressed the causes of any workforce inequality. However, not all staff had received equality and diversity training. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

Governance arrangements

There were some systems to support good governance and management. However, improvements were required.

- There was limited evidence of clinical governance to ensure effective monitoring and assessment of the overall quality of the service.
- We saw individual patients were monitored, but there was limited evidence of overall quality improvement activity. For example, clinical audits had not been carried out. There were no medicine audits to monitor the quality of prescribing.
- Staff were clear on their roles and accountabilities.
- Service specific policies were available to all staff.

Managing risks, issues and performance

There were some processes in place for managing risks, issues and performance. However, improvements were required.

- There were some arrangements for identifying, recording and managing risks, issues and implementing

Are services well-led?

mitigating actions. However, monitoring of specific areas such as the calibration of clinical equipment, fire drills, emergency medicines and the management of legionella was not managed appropriately.

- The service had not conducted a formal risk assessment about access to the emergency equipment.
- They did not have any formal monitoring system in place to ensure that adequate water temperature checks had been undertaken by the host who was responsible for managing the premises.
- The service had processes to manage current and future performance. Leaders had oversight of safety alerts and complaints.
- The service held regular staff team meetings.
- The service had plans in place and had trained staff for major incidents.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Care and treatment records were complete, legible and accurate, and securely kept.
- The doctor responsible for monitoring patients' care was able to access previous consultation notes.
- There were robust arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.
- The service was registered with the Information Commissioner's Office.

Engagement with patients, the public, staff and external partners

The service involved patients, the public, staff and external partners to support high-quality sustainable services.

- The service encouraged and valued feedback from patients.

- The service had conducted a patient survey in February 2019. The service had received 38 responses. The results were highly positive about the quality of service patients received and high satisfaction levels.
- The service had implemented changes to improve the service. For example, the service had redecorated the scan room following the feedback from the patients.
- The doctor had collected 360-degree feedback from other clinical colleagues.
- Staff meetings were held regularly which provided an opportunity for staff to engage with the service.
- The service was transparent, collaborative and open with stakeholders about performance.

Continuous improvement and innovation

There was evidence of systems and processes for learning, continuous improvement and innovation. However, improvements were required.

- The service made use of internal reviews of complaints. Learning was shared and used to make improvements.
- Leaders encouraged staff to take time out to review individual and team objectives, processes and performance. However, we found gaps in staff training.
- The doctor had attended regular meetings with the other clinicians working with bio-identical hormones and functional medicines, which included discussion regarding the different approaches, impacts, side effects and developments related to the use of bio-identical hormones. This enabled the various experiences to be shared among the clinicians and included discussion regarding the previous interactions, consultations and assessment in complex cases, use of good practices and share the learning.
- The doctor had attended various health conferences and was involved in research studies with other clinical fellows.

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 the service provider was not meeting. The provider must send CQC a report that says what action it is going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Treatment of disease, disorder or injury	<p data-bbox="810 663 1385 730">Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p data-bbox="810 757 1321 786">How the regulation was not being met:</p> <p data-bbox="810 813 1517 992">The service did not have effective governance, assurance and auditing processes to enable the registered person to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk.</p> <p data-bbox="810 1019 1098 1048">In particular, we found:</p> <ul data-bbox="821 1075 1517 2000" style="list-style-type: none"><li data-bbox="821 1075 1460 1216">• There was limited evidence of overall quality improvement activity. However, individual patients were monitored to review the effectiveness and appropriateness of the care provided.<li data-bbox="821 1227 1517 1368">• The service had not always ensured that clinical equipment was calibrated and maintained according to manufacturers' instructions to ensure it was safe to use and was in good working order.<li data-bbox="821 1395 1513 1536">• The service had no documentary evidence of having risk assessed whether they would have timely access to suitable emergency equipment to deal with an urgent medical situation.<li data-bbox="821 1547 1474 1688">• The service was required to carry out more frequent checks to ensure medical oxygen and a defibrillator were fit to use and maintain written records of these checks.<li data-bbox="821 1715 1513 1888">• There were some emergency medicines available in the service and there was no formal documented risk assessment to demonstrate that they had considered the possibility which emergency medicines might be needed, and how to ensure timely administration.<li data-bbox="821 1899 1517 2000">• The service had not developed a documented safeguarding children policy, which could be required if they were dealing with a child safeguarding concern.

This section is primarily information for the provider

Requirement notices

- The service was unable to demonstrate they had adequate health and safety arrangements in place to ensure the management of legionella in the premises.
- Fire drills were not carried out.
- There was no information available on the service's website which informed people about the risks associated with the use of an unlicensed medicine.
- A spill kit was not available.

This was in breach of regulation 17(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Regulated activity

Diagnostic and screening procedures

Treatment of disease, disorder or injury

Regulation

Regulation 18 HSCA (RA) Regulations 2014 Staffing

How the regulation was not being met:

We found the registered person had not ensured the provision of appropriate training and support so all staff have the competence and skills which are necessary for the work to be performed by them.

In particular, we found:

- The service was unable to provide documentary evidence that all staff had received training relevant to their role that included: safeguarding children, safeguarding adults, infection control, basic life support, health and safety, infection control, equality and diversity, chaperone, information governance and fire safety awareness training.

This was in breach of regulation 18(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.