

Lolavista Limited

London Bioidentical Hormones

Inspection report

3rd Floor
4 Harley Street
London
W1G 9PB
Tel: 020 3303 0237
Website: www.londonbioidenticalhormones.com

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Overall summary

We carried out an announced comprehensive inspection on 7 February 2019 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.

London Bioidentical Hormones 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 for women.

The principal GP 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.

Six 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 principal GP was approachable, committed and caring. They said the staff were helpful and treated them with dignity and respect.

Summary of findings

Our key findings were:

- The service had specialised in individualised bioidentical hormone replacement therapy and functional medicine for women. Patients were treated with unlicensed compounded medicines and systems were in place to ensure this was carried out safely.
- There was evidence of quality improvement activity including clinical audit.
- Consultations were comprehensive and undertaken in a professional manner.
- Consent procedures were in place and these were in line with legal requirements.
- There was an infection prevention and control policy and procedures were in place to reduce the risk and spread of infection.
- The service was unable to demonstrate they had adequate health and safety arrangements in place to ensure fire safety and management of legionella in the premises.
- The service had not carried out a risk assessment or developed a service specific fire evacuation plan to identify how staff could support patients with mobility problems to vacate the premises.
- All emergency medicines were not available in the service and there was no formal documented risk assessment as to why they were not required.

- 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.
- The service had proactively gathered feedback from the patients.
- Information about services and how to complain was available.
- The provider was aware of and complied with the requirements of the Duty of Candour.

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 could make improvements and should:

- Carry out more frequent checks to assure medical oxygen and a defibrillator are fit to use and maintain written records of these checks.
- Consider how to improve access to patients with hearing difficulties.

Dr Rosie Benneyworth BM BS BMedSci MRCGP

Chief Inspector of Primary Medical Services and Integrated Care

London Bioidentical Hormones

Detailed findings

Background to this inspection

London Bioidentical Hormones 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 for women.

Lolavista Limited is a private limited company and the provider of this independent healthcare service. The service is renting a consultation room in shared premises at The Hale Clinic. The service is run by a principal GP and did not employ any staff. The service had a contract with an external organisation to provide administration services through virtual secretaries. The principal GP is performing duties as a medical director and responsible for the management and day to day running of the patient service.

Services are provided from: 3rd Floor, 4 Harley Street, London, W1G 9PB.

On 7 February 2019, our inspection team was led by a CQC lead inspector. The team included a GP specialist adviser.

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

The clinic is open between 9am to 5pm on Monday, Tuesday and Wednesday. Telephone calls are answered by virtual secretaries from 8am to 6pm Monday to Friday and from 9am to 2pm on every Saturday.

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.

Pre-inspection information was gathered and reviewed before the inspection. We spoke with the principal GP. 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.

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

Safety systems and processes

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

- The service conducted safety risk assessments. Safety policies were regularly reviewed. The service had systems to safeguard vulnerable adults from abuse. Policies were regularly reviewed and were accessible.
- The principal GP understood their responsibilities to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- The service did not employ any staff. However, they had a recruitment policy in place to carry out staff checks, including checks of professional registration where relevant, on recruitment and on an ongoing basis. 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).
- The principal GP received up-to-date safeguarding and safety training appropriate to their role. They knew how to identify and report concerns. The principal GP informed us they would request a building reception staff to act as a chaperone if required, and would ensure that staff who acted as a chaperone was trained for the role and had received a DBS check.
- There was an effective system to manage infection prevention and control. The service was renting space in shared premises and the contractor was responsible for cleaning the premises. We observed that appropriate standards of cleanliness and hygiene were followed. The provider had carried out an infection control audit.

- There were systems for safely managing healthcare waste.
- The service had a business continuity plan in place.
- A panic alarm was not installed to alert other healthcare staff in an emergency although it was observed that there was a call system in place to raise an alarm with the building staff and the consulting room was in close proximity to the reception. Therefore, if an emergency arose, a call for help could be heard.
- On registering with the service in person, and at each consultation patients confirmed their identity either face to face or verbally on the telephone or video call and the principal GP had access to the patient's previous records held by the service. The service did not treat children at the time of our inspection.
- Patient's identity was verified by the provision of bank account (via PayPal) or credit card details, provision of date of birth and UK address, and by email verification. The first consultation was always face to face.

Risks to patients

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

- The principal GP understood their responsibilities to manage emergencies on the premises and to recognise those in need of urgent medical attention. The principal GP knew how to identify and manage patients with severe infections, for example, sepsis.
- When there were changes to services the practice assessed and monitored the impact on safety.
- The principal GP had professional indemnity insurance that covered the scope of their practice.

Information to deliver safe care and treatment

The principal GP 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 in an accessible way. Patient records were stored securely using an electronic record system. The principal GP used their laptop to log into the operating system, which was a secure programme.
- The service had systems for sharing information with external professionals and other agencies to enable them to deliver safe care and treatment.

Are services safe?

- The service had a system in place to retain medical records in line with DHSC guidance in the event that they cease trading.
- The service made appropriate and timely referrals in line with protocols and up to date evidence-based guidance.

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 medicine and equipment minimised risks. However, medical oxygen and a defibrillator were only checked twice a year and written records of these checks were not maintained.
- There was one emergency medicine (Adrenaline) available at the service. The principal GP informed us they had considered which emergency medicines were required and decided to keep only this emergency medicine. 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 principal GP 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 provider only used UK compounding pharmacies that were registered with the General Pharmaceutical

Council in the UK. They turned powdered bioidentical hormones into medical preparations such as creams, gels, lozenges and pessaries and offered bases that were hypoallergenic and paraben free.

- The provider offered services to female patients who were aged 18 years and over for the treatment of issues related to the women's health and male patients who were aged 50 years and over.
- Most of the private prescriptions were processed electronically. Some of the private prescriptions were printed on the letterhead which included a company name, logo and other necessary information. These paper prescriptions were prescribed and signed by the principal GP.

Track record on safety

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.
- The service had a fire risk assessment in place. However, it did not include the actual date of the risk assessment and name of the assessor. There was no evidence available to demonstrate that the fire risk assessment was carried out by a competent person. There was no documented fire evacuation plan to identify how staff could support patients with mobility problems to vacate the premises. There was no documentary evidence available to demonstrate that regular fire drills were carried out.
- The host was responsible for carrying out fire safety checks. However, smoke alarm checks were not documented and we noted fire extinguishers were not serviced regularly. We found a fire extinguisher which was last serviced in January 2004. The fire system was serviced on 31 January 2019.
- Electrical installation condition inspection had not been carried out.
- The service had carried out a legionella risk assessment on 31 January 2019 and they were waiting for the report. The service had not carried out regular water temperature checks to ensure the effective management of legionella. (Legionella is a term for a particular bacterium which can contaminate water systems in buildings). The service informed us they had sent a water sample for an external analysis on 5 February 2019 and were waiting for the results.

Are services safe?

- The service ensured that equipment was safe and maintained according to manufacturers' instructions. All clinical equipment was checked and calibrated to ensure clinical equipment was safe to use and was in good working order.
- We noted that the safety of electrical portable equipment was assessed at the premises to ensure they were safe to use.

Lessons learned and improvements made

- The principal GP 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 principal GP 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 principal GP had signed up to receive patient and medicine safety alerts. The principal GP provided examples of alerts they had received but there were no examples of alerts being acted on as none had been relevant.

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 provider assessed needs and delivered care in line with relevant and current evidence-based guidance and standards such as the National Institute for Health and Care Excellence (NICE), the Royal College of Obstetricians and Gynaecologists (RCOG) and British Menopause Society (BMS) best practice guidelines.

- The service ensured that all patients must be seen face to face for their initial consultation and in person at least annually thereafter.
- We reviewed three 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.
- The service used a comprehensive assessment process including a 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.
- The service had arrangements to review the treatment of patients on long-term medicines.

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 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 principal GP 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 (20 minutes) one to two weeks later to discuss the scan or blood test results.
- The service offered regular progress reviews after two months, six months and 10 months to monitor and adjust the treatment according to a patient's symptoms and needs. The principal GP had access to all previous notes.
- Patients were able to contact the principal GP to arrange a five minutes free telephone consultation to discuss any concerns.
- The principal GP advised patients what to do if their condition got worse and where to seek further help and support.

The service was actively involved in quality improvement activity.

- The service used information about care and treatment to make improvements.
- We reviewed three clinical audits carried out in the last 12 months. The service made improvements through the use of completed audits. Clinical audits had a positive impact on quality of care and outcomes for patients. For example, the service had carried out an audit to identify the female patients aged 50 years old or over who had not attended a breast screening appointment in the last three years. The initial audit in November 2017 had identified four out of 51 female patients aged 50 years old or over who had no information documented in their medical notes regarding breast screening in the last three years. The service had contacted all four patients, reminded them to arrange the screening appointment and updated their medical notes. The service had added an alert into the notes template prompting the principal GP to ask about the last breast screening during consultations. The service had carried out a second audit in October 2018, checked a random sample of 50 sets of medical notes and found that 100% of female patients over 50 years old had the relevant information documented regarding the last breast screening.
- The service had carried out prescribing audits to monitor the individual prescribing decisions and to identify the appropriateness of their medicines. Overall clinical outcomes for patients were monitored.

Are services effective?

(for example, treatment is effective)

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. Patients were able to access their pathology results through the patient portal on the service website.

Effective staffing

- The service was run by a principal GP and did not employ any staff.
- The principal GP was registered with the General Medical Council (GMC) the medical professionals' regulatory body with a licence to practice.
- The principal GP 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 principal GP 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 clinic). The principal GP was following the required appraisal and revalidation processes.
- The principal GP had received an appraisal in February 2018.
- The principal GP had attended role-specific training and demonstrated proof of their ongoing professional development.
- The principal GP had received training that included: safeguarding of vulnerable adults, safeguarding children level three, basic life support, fire safety awareness, health and safety, infection control and equality and diversity.
- The provider had a contract with an external organisation to provide administration services through virtual secretaries. The provider had developed a reception manual to assist the virtual secretaries to deal with telephone and email queries and book appointments. All medical queries were answered by the principal GP. Policies and procedures were saved online in the cloud based server and accessible to the virtual secretaries.

Coordinating patient care and information sharing

- If a patient needed further examination they were directed to an appropriate agency; we noted examples of patients being signposted to their own GP or to their nearest A&E department as well as referral letters to private consultants.
- 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. We saw the example of consultation notes having been shared with the GP with the appropriate patient 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 service had a range of information available on their website. For example, there was information available regarding dealing with depression, stress, memory loss, weight loss and a number of blogs discussing women's health issues.
- Nutritional supplements had been recommended by the principal GP to promote a healthy life style and could be ordered from the professional healthcare websites and did not require a formal prescription.
- The principal GP had prescribed nutrients and supplements to treat hot flushes, mood disorders, insomnia, depression and anxiety in menopause.
- Nutritional supplements had been recommended to provide support for healthy digestive, immune and circulatory system and to maintain blood sugar levels.

Consent to care and treatment

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

- The principal GP understood the requirements of legislation and guidance when considering consent and decision making.
- The principal GP 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.

Are services effective?

(for example, treatment is effective)

- The manufacturer's patient information leaflet provided with the medicine only referred to the licensed use of that medicine. The provider informed us that further 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, the consent form did not include information about the risks associated with the use of an unlicensed medicine. The provider acted proactively, reviewed contents of the consent form and submitted the new consent form to us a day after the inspection. In addition, there was a statement 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?

Our findings

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

Kindness, respect and compassion

Staff treated patients with kindness, respect and compassion.

- The principal GP we spoke with was aware of their responsibility to respect people's diversity and human rights.
- We did not speak to patients directly on the day of the inspection. However, we spoke with two patients on the telephone two days after the inspection. We received four completed Care Quality Commission comment cards. Feedback from patients was positive about the way staff treat people.
- Patients said they felt the provider offered an excellent service and the principal GP 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 the principal GP responded compassionately when they needed help and provided support when required.
- We reviewed patient feedback available online which was positive.
- The service gave patients timely support and information.

Involvement in decisions about care and treatment

The principal GP helped patients to be involved in decisions about care and treatment.

- Interpretation services were available for patients who did not have English as a first language.
- The service gave patients clear information to help them make informed choices including information on the clinic'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.
- Patients told us they felt listened to and supported by the principal GP and had sufficient time during consultations to make an informed decision about the choice of treatment available to them.
- Feedback suggested that patients felt diagnosis and therapy options or treatments were explained clearly to them.
- The service did not provide a hearing induction loop.

The service had carried out an internal patient satisfaction survey via an external survey website in December 2018. We saw 191 patients participated in the survey and results showed the service was performing well and patients were satisfied with the service. For example:

- 97% of patients said the principal GP was good at listening during the consultations.
- 96% of patients said the principal GP was good at involving them in decisions about their care and treatment.
- 94% of patients said the principal GP was good at providing the opportunity to ask questions during the consultations.

Privacy and Dignity

The service respected patients' privacy and dignity.

- The principal GP recognised the importance of people's dignity and respect.
- The service had a confidentiality policy in place and systems were in place to ensure that all patient information was stored and kept confidential.
- We were told that the principal GP undertook consultations in a private space and were not to be disturbed at any time during their working time.

Results from the internal patient satisfaction survey showed:

- 94% of patients described the overall handling of confidential medical information as excellent or good.

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

The service organised and delivered services to meet patients' needs.

- 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 consultations were available for patients that chose to use this service.
- The provider offered consultations to anyone who requested and paid the appropriate fee, and did not discriminate against anyone.
- 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 cancellation policy.
- The service website was well designed, clear and simple to use featuring regularly updated information. The website also allowed registered patients to access their records via a patient portal.
- They provided services to patients with an ethos of providing individualised care and treatment, considering and respecting the wishes of its patients.
- The provider offered services to female patients who were aged 18 years and over for the treatment of issues related to the women's health and male patients who were aged 50 years and over.

Timely access to the service

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

- Patients had timely access to initial assessment, test results, diagnosis and treatment.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- 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 principal GP informed us that the initial consultation appointment was only offered face to face for 45 minutes. Follow up consultation appointments (15 to 20 minutes) were usually available within two working days.
- Appointments were available on a pre-bookable basis. The service provided consultations face to face, via telephone and video calls. Consultations were available between 9am to 5pm on Monday, Tuesday and Wednesday. In addition, telephone consultations and video consultations could be booked on Thursday and Friday if required. The provider was flexible to accommodate telephone consultations and video consultations until 6.30pm Monday to Friday if required for working patients who could not attend during normal opening hours. The practice published information about this on the service website and on the patient leaflet.
- Patients could access the service in a timely way by making their appointment over the telephone. Telephone calls were answered by virtual secretaries from 8am to 6pm Monday to Friday and from 9am to 2pm on every Saturday.
- 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.
- Patients reported that the appointment system was easy to use. Patient feedback we received confirmed they had flexibility and choice to arrange appointments in line with other commitments.

Results from the internal patient satisfaction survey (from December 2018) showed:

- 95% of patients described their experience of making an appointment as easy.

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.

- The service had a complaints policy and there were procedures in place for handling complaints.

Are services responsive to people's needs? (for example, to feedback?)

- The principal GP was a designated responsible person to handle all complaints. The service had an arrangement in place with the head of virtual secretaries who would investigate the complaint if any complaint was made against the principal GP.
- Information about how to make a complaint or raise concerns was available on the service's web site and on the patient's leaflet. We saw this information included the complainant's right to escalate the complaint to the Independent Doctors Federation (IDF), General Medical Council (GMC) and the Care Quality Commission (CQC) if dissatisfied with the response.
- The service had received one complaint in the last 12 months and found that complaint had been addressed in a professional manner and the patient received a timely response. There was evidence that the service had provided an apology and refunded the consultation charges. However, complaint response did not include information of the complainant's right to escalate the complaint if dissatisfied with the response.
- The service learned lessons from the individual complaint and took steps to improve time management in the future.

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.

Leadership capacity and capability

The principal GP had the capacity and skills to deliver high-quality, sustainable care.

- The principal GP had the experience, capacity and capability to run the service and ensure patients accessing centre received high-quality assessment and care.
- The principal GP, who was also a medical director and a UK based GMC registered doctor, had overall responsibility for any medical issues arising.
- The principal GP was knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them.

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 mission statement which included the service's aim and objectives. This included finding the root cause of disease through addressing imbalances and dysfunctions with a combination of bio-identical hormones, nutrition and supplements, and the best of conventional medicine. The key objective was to provide bespoke patient-centred healthcare service to adults which meets and exceeds patients' expectations and to ensure compliance with the legal requirements.
- The service monitored progress against delivery of the strategy.

Culture

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

- 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.

Governance arrangements

- The service had a governance framework which supported the delivery of the strategy and good quality care.
- There was a range of service specific policies which were accessible and these had recently been updated.

Managing risks, issues and performance

There were processes in place for managing risks, issues and performance. However, some improvements were required to improve the safety of the premises.

- There was an effective, process to identify, understand, monitor and address most current and future risks including risks to patient safety.
- The service had processes to manage current and future performance.
- The service informed us they had regular meetings every two months with the head of virtual secretaries to review the performance.
- The principal GP had oversight of safety alerts, incidents, and complaints.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was clear evidence of action to change services to improve quality.
- The service had plans in place for major incidents.

Appropriate and accurate information

The service acted on appropriate and accurate information.

- Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients.
- The information used to monitor performance and the delivery of quality care was accurate and useful. There were plans to address any identified weaknesses.
- Care and treatment records were complete, legible and accurate, and securely kept.

Are services well-led?

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

- 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.

Results from the internal patient satisfaction survey (from December 2018) showed:

- 93% of patients said they were satisfied with the information available about the service on the provider's website including fees and directions.

Engagement with patients, the public, staff and external partners

The service involved patients to support high-quality sustainable services.

- The service encouraged and valued feedback from patients.
- We saw a number of positive comments documented on the online review websites at the time of our inspection.
- The service had conducted a patient survey via an external survey website in December 2018. The service had received 191 responses. The results were highly positive about the quality of service patients received and high satisfaction levels.

- The principal GP had collected 360-degree feedback from other clinical colleagues.

Continuous improvement and innovation

- The service consistently sought ways to improve.
- The principal GP had attended regular meetings held every two months at the Royal Society of Medicines with the other clinicians working with bio-identical hormones, 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 enable them and the service to better monitor and improve diagnoses.
- The principal GP had attended regular meetings held every two months at the local clinic with the other clinicians working with functional medicines, which included discussion regarding the previous interactions, consultations and assessment in complex cases, use of good practices and share the learning.
- The principal GP had been involved in research studies with other clinical fellows specialising in the use of bio-identical hormones therapy.
- The principal GP had attended various health conferences related to women's health.

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	<p data-bbox="815 658 1485 725">Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p data-bbox="815 748 1321 784">How the regulation was not being met:</p> <p data-bbox="815 806 1511 913">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:</p> <ul data-bbox="815 936 1517 1491" style="list-style-type: none"><li data-bbox="815 936 1517 1084">• The service was unable to demonstrate they had adequate health and safety arrangements in place to ensure the fire safety and the management of legionella in the premises.<li data-bbox="815 1084 1517 1232">• The service had not carried out a risk assessment or developed a service specific fire evacuation plan to identify how staff could support patients with mobility problems to vacate the premises.<li data-bbox="815 1232 1517 1379">• The service was unable to provide documentary evidence to demonstrate that fixed electrical installation checks of the premises had been carried out.<li data-bbox="815 1379 1517 1491">• All emergency medicines were not available in the service and there was no formal documented risk assessment as to why they were not required. <p data-bbox="815 1514 1485 1621">This was in breach of regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.</p>