

Lolavista Limited

# London Bioidentical Hormones

## Inspection report

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Date of inspection visit: 15 November 2017

Date of publication: 29/12/2017

## Overall summary

We carried out an announced comprehensive inspection on 15 November 2017 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 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.

## **Background**

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 meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

This was the first inspection undertaken at this service.

London Bioidentical Hormones is an independent clinic in the 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 service is renting a consultation room in a shared premises at The Hale Clinic. The service is run by a principal GP and did not employ any staff. Lolavista Limited is a private limited company and the provider of this independent healthcare service. The principal GP is performing duties as a medical director and responsible for the management and day to day running of the patient service.

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

# Summary of findings

registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

Two patients we spoke with on the telephone were positive about the care and treatment offered by the principal GP. Patients said they were satisfied with the standard of care received and thought the principal GP was approachable, committed and caring. As part of our inspection, we also asked for CQC comment cards to be completed by patients prior to our inspection. However, we did not receive any completed comment cards.

## Our key findings were:

- The provider 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.
- Consent procedures were in place and these were in line with legal requirements.
- Systems were in place to protect personal information about patients. The service was registered with the Information Commissioner's Office (ICO).
- Identity checks relied on a verification of bank account (via PayPal) or credit card details, provision of a date of birth and UK address, and by email verification.
- 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 did not employ any staff and they had a contract with an external organisation to provide the administration services through virtual secretaries.
- There was some evidence of quality improvement activity including clinical audit.
- Prescribing decisions were monitored by the principal GP to prevent any misuse of the service by patients. Overall clinical outcomes had been monitored.
- Information about services and how to complain was available.
- The service had proactively gathered feedback from the patients.
- Safety systems and processes were in place although no infection control audits had been carried out.

There were areas where the provider could make improvements and should:

- Carry out an infection control audit.
- Review the contents of the service's website and include the information about the risks associated with the use of an unlicensed medicine.
- Review quality improvement initiatives which may include completed clinical audits.
- Review the gaps in the following training: fire safety awareness, infection control and health and safety.
- Consider arranging a translation service and review the information available for patients who do not speak English.
- Consider how to improve access to patients with hearing difficulties.

# Summary of findings

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### **Are services safe?**

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

We found areas where improvements should be made relating to the safe provision of treatment. This was because:

- The provider had not carried out an infection control audit. Other infection control measures were in place and were seen to be working effectively.
- A robust patient identification system was in place.
- Treatment with functional medicines and unlicensed compounded medicines was safely managed.
- There were systems and processes in place to keep patients safe and safeguarded from abuse.
- There were systems in place to protect all patient information and records were stored securely.
- There was a system for the reporting of significant events and incidents. However, we could not assess its effectiveness as no incidents had been reported.
- There were systems in place to meet health and safety legislation.
- The provider was aware of and complied with the requirements of the Duty of Candour and encouraged a culture of openness and honesty.

### **Are services effective?**

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

We found areas where improvements should be made relating to the effective provision of treatment. This was because:

- The service had not carried out any prescribing audits to monitor the individual prescribing decisions. The service had carried out three audits, but none of them was repeated.
- Individual prescribing decisions and consultation records were monitored informally by the principal GP. Overall clinical outcomes for patients had been monitored by the provider.
- Patients consented to care and treatment by agreeing to the provider's terms and conditions; during individual consultations, which covered the use of unlicensed medicines.
- The service's web site contained information to help support patients lead healthier lives. However, there was no statement on the service's website which informed people about the risks associated with the use of an unlicensed medicine.
- There were training and appraisal arrangements in place to ensure staff had the skills, knowledge and competence to deliver effective care and treatment. However, we identified gaps in the following training: fire safety awareness, infection control and health and safety.
- We observed that the principal GP assessed patients' needs and delivered care in line with relevant and current evidence based guidance and standards, for example, National Institute for Health and Care Excellence (NICE) and British Menopause Society (BMS) best practice guidelines.
- There was an appropriate system for recording and updating patient care and treatment information.
- The service had arrangements in place to coordinate care and share information appropriately for example when patients were referred to other services or to their own GP.

### **Are services caring?**

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

# Summary of findings

- Systems were in place to ensure that all patient information was stored and kept confidential. The service was registered with the Information Commissioner's Office (ICO).
- According to patient feedback, services were delivered with compassion, dignity and respect and they were involved in decisions about their care and treatment.
- Information for patients about the services was available.
- Translation services were not available for patients who did not have English as a first language.
- The service did not provide a hearing induction loop.

## **Are services responsive to people's needs?**

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

- There was information available to patients to demonstrate how the service operated. Patients could access help from the service.
- Patients were able to request consultations by email or telephone via virtual secretaries.
- There was timely access to appointments once requested. Appointments were available on a pre-bookable basis. The service provided consultations face to face, via telephone and video calls. The initial consultation appointment was only offered face to face.
- There was a complaints policy which provided information about handling complaints from patients.

## **Are services well-led?**

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

- There was a clear ethos of patient centred care.
- Governance arrangements were in place and enabled the day to day running of the service. However, quality improvement was informal at the time of our inspection.
- There were arrangements for identifying, recording and managing risks, issues and implementing mitigating actions.
- Service specific policies were available.
- Patient feedback was encouraged and considered in the running of the service.

# London Bioidentical Hormones

## Detailed findings

### Background to this inspection

On 15 November 2017, our inspection team was led by a CQC Lead Inspector. The team included a GP specialist advisor.

Pre-inspection information was gathered and reviewed before the inspection. We spoke with the registered manager. We looked at records related 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 providing safe care in accordance with the relevant regulations.

### Safety systems and processes

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

- The service 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 a space in a shared premises and the contractor was responsible for cleaning the premises. We observed that appropriate standards of cleanliness and hygiene were followed. However, the provider had not carried out an infection control audit.
- The practice ensured that facilities and equipment were safe and that equipment was maintained according to manufacturers' instructions. There were systems for safely managing healthcare waste.
- The service had a business continuity plan in place.
- The provider was unable to provide a documentary evidence of a lone worker risk assessment. 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 rooms were in close proximity to one another. 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 a 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 a professional indemnity insurance that covered the scope of their practice.

### Information to deliver safe care and treatment

- Individual care records were written and managed in a way that kept patients safe. Patient records 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 was registered with the Information Commissioner's Office.
- The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.
- Risks related to patients' diagnoses and other health and wellbeing risks were recorded in patients' records.
- Referral letters included all of the necessary information.

### Safe and appropriate use of medicines

# Are services safe?

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

- The systems for managing medicines, including medical gases, and emergency medicines and equipment minimised risks.
- 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. The principal GP informed us they were not registering new male patients and mostly focussing on the issues related to the women's sexual health.
- 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.

- There were comprehensive risk assessments in relation to safety issues.
- The service was renting a space in a shared premises and they had an effective monitoring system to ensure that regular safety checks had been undertaken by the contractor who was responsible for managing the premises.
- The service had up to date fire risk assessment in place and the contractor was carrying out regular fire safety checks.
- The service had up to date legionella risk assessment in place and the contractor was carrying out regular water temperature checks. (Legionella is a term for a particular bacterium which can contaminate water systems in buildings).

## Lessons learned and improvements made

- There was an incident reporting policy for staff to follow and there were procedures in place for the reporting of incidents and significant events. However, we could not assess its effectiveness as no incidents had been reported.
- The 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) 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 two 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.
- The principal GP advised patients what to do if their condition got worse and where to seek further help and support.

### 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.

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.

The provider had carried out some clinical audits.

- 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 reviewed three clinical audits carried out in the last 12 months. However, the provider had not carried out a repeat clinical audit cycle.
- The provider had initiated one audit to identify the female patients aged 50 years old or over who had not attended the breast screening appointment in the last three years. This audit in November 2017 identified nine out of 51 female patients aged 50 years old or over who had not attended the breast screening appointment in the last three years. However, out of them three patients were just turned 50 years old and waiting for their



# Are services effective?

## (for example, treatment is effective)

appointment. Four patients had refused to take part in the screening process. Two patients were overdue and the service had reminded them to arrange the screening appointment.

- A second audit was initiated to identify patients who had consent forms missing in their electronic patient records. During this audit the provider had checked electronic records of 102 patients and identified 29% consent forms were missing. The provider had implemented the changes and was requesting all patients to complete the consent forms.
- Findings were used by the practice to improve services. For example, the practice had carried out an audit in January 2017 to identify why patients had cancelled or missed the pre-book appointments. This audit had identified some confusion with the online booking process. The provider had reviewed the appointment booking system and implemented the changes to streamline the booking process. The provider had reinforced the 48 hours cancellation notice. The principal GP informed us they had not carried out a follow up audit but noticed a significant improvement.

### 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 recognised as the nationwide voice of independent doctors in all matters relating to private medicine, their education and revalidation).
- The principal GP had a current 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 January 2017.
- 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, chaperoning, and equality and diversity. However, we identified that the principal GP had not completed formal training in fire safety awareness, infection control and health and safety. The principal GP had demonstrated that they had gone through the relevant handouts and information material which was saved within the service online folders.

- The provider had a contract with an external organisation to provide the 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 (or links to research or blogs). 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 the healthy life style and could be ordered from the professional healthcare websites and did not require a formal prescription.

# Are services effective?

(for example, treatment is effective)

- 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 principal GP understood and sought patients' consent to care and treatment in line with legislation and guidance. If a patient's mental capacity to consent to care or treatment was unclear we were told the principal GP would assess the patient's capacity and record the outcome of the assessment.
- The service had a consent policy in place and the principal GP had received training on consent.
- 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 a medicine for use outside of its licence. However, there was no statement 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

- 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.
- 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.
- We did not receive any completed Care Quality Commission comment cards.

The provider had carried out an internal patient satisfaction survey via an external survey website in February 2017. We saw 91 patients participated in the survey (from August 2016 to February 2017) and results showed the service was performing well and patients were satisfied with the extended hours service. For example:

- 89% of patients said they would recommend the service to friends and family if they needed similar care or treatment.

### Involvement in decisions about care and treatment

- The service gave patients clear information to help them make informed choices including information on the clinics 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.
- We found that interpretation services were not available for patients who did not have English as a first language. The principal GP 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.

Results from the internal patient satisfaction survey (from February 2017) showed:

- 98% of patients said the principal GP was good at listening during the consultations.
- 97% of patients said the principal GP was good at involving them in decisions about their care and treatment.
- 97% of patients said the principal GP was good at providing the opportunity to ask questions during the consultations.

### Privacy and Dignity

- 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 (from February 2017) showed:

- 95% of patients described the overall handling of the 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

- Patient's individual needs and preferences were central to the planning and delivery of tailored services. Services were flexible, provided choice and ensured continuity of care, 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 a 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. The principal GP informed us they were not registering new male patients and mostly focussing on the issues related to the women's sexual health.

### Timely access to the service

- The provider 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. We noted the next initial consultation appointment was available on 27 November 2017. 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 8pm 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.
- 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 February 2017) showed:

- 97% of patients described their experience of making an appointment as easy.

### Listening and learning from concerns and complaints

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

- The practice had a complaints policy and there were procedures in place for handling complaints.
- 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 was available on the service's web site and on the patients leaflet. We saw this information included the complainant's right to escalate the complaint to the Independent Doctors Federation (IDF), General Medical

# Are services responsive to people's needs?

(for example, to feedback?)

Council (GMC), Independent Healthcare Sector Complaints Adjudication Service (ISCAS) and the Care Quality Commission (CQC) if dissatisfied with the response.

- The provider had never received a formal complaint since the service opened.

# 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 provider had a clear vision to provide a high-quality responsive service.
- The provider had a mission statement which included 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 a bespoke patient-centred healthcare service to adults which meets and exceeds patients' expectations and to ensure compliance with the legal requirements.

### 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.
- There were no repeat clinical audits demonstrating improved outcomes for patients and infection control audits were not in place to monitor infection control standards. There was no medicine audit to monitor the quality of prescribing.

### Managing risks, issues and performance

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The service identified, assessed and managed clinical and environmental risks related to the service provided.
- There were systems in place to monitor the overall performance of the service.
- There was no specific prescribing audit activity, but individual patients on prescribed medicines were monitored to identify the appropriateness of their medicines.
- The provider informed us they had regular meetings every two months with the head of virtual secretaries to review the performance.

### Appropriate and accurate information

The service acted on the appropriate and accurate information.

- Patient assessments, treatments and medications, including ongoing reviews of their care, were recorded on a secure electronic system. We reviewed two anonymised assessment reports where a diagnosis was made. We found that the assessments included clear information and recommendations. The principal GP responsible for monitoring patients' care was able to access notes from all the previous consultations.
- Care and treatment records were complete, legible and accurate, and securely kept.
- The provider had supporting documents regarding data storage from information commissioners office (ICO) and had protocols for safe sharing and storage of sensitive information. The provider was also registered with the ICO.

# Are services well-led?

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

Results from the internal patient satisfaction survey (from February 2017) 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 encouraged and valued feedback from patients. They acted to improve services on the basis of this feedback.

- We saw a number of positive comments documented on the online review websites at the time of our inspection.
- There were many examples of compliments received by the service. For example, we saw several compliments relating to the caring nature of the principal GP and the clear explanations around the assessment process and outcomes.
- The service had conducted a patient survey via an external survey website in February 2017.
- Comments and feedback were encouraged and reviewed. The provider had implemented changes to improve the service following the feedback from the patients. For example, the contents of appointment confirmation email had been reviewed and it included clear information regarding the cost of the services and the cancellation policy.

- The principal GP had collected a 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. We saw meeting minutes 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 Hale Clinic with the other clinicians working with functional medicines. We saw meeting minutes 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 a two day women's health conference in London.