

# London Bioidentical Hormones

## Inspection report

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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

Good 

Are services safe?

Good 

Are services effective?

Good 

Are services caring?

Good 

Are services responsive to people's needs?

Good 

Are services well-led?

Good 

# Overall summary

**This service is rated as Good overall.** (Previous inspection 7 February 2019 – we found that the service was not providing safe care in accordance with the relevant regulations. We issued a requirement notice for Regulation 12 Health and Social Care Act 2008, Regulations 2014 Safe care and treatment.

The key questions are rated as:

Are services safe? – Good

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Good

We carried out an announced comprehensive inspection of London Bioidentical Hormones on 23 September 2021. 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 service, which provides a range of bespoke healthcare treatments 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.

This service is registered with CQC under the Health and Social Care Act 2008 in respect of some, but not all, of the services it provides. There are some exemptions from regulation by CQC which relate to particular types of regulated activities and services and these are set out in Schedule 1 and Schedule 2 of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. London Bioidentical Hormones Limited provides nutritional therapy which is not within CQC's scope of registration. Therefore, we did not inspect or report on this service.

## **Our key findings were:**

- There was evidence of quality improvement activity including clinical audit.
- The provider had a clear vision to provide a safe and high-quality service.
- Appointments were available on a pre-bookable basis. The service provided consultations via video and telephone calls.
- The service had proactively gathered and acted on feedback from their patients.
- Information about the service and how to complain was provided to patients.
- Recruitment checks were carried out appropriately and the provider monitored the training of staff associated with the service.
- Consent procedures were in place and these were in line with legal requirements.
- The provider had access to interpretation services for patients whose first language was not English.
- Systems were in place to protect patients' personal information. • Information about services and how to complain was available and easy to understand.

# Overall summary

- The provider was aware of and complied with the requirements of the Duty of Candour.
- Thirty-three people provided feedback about the service. Thirty-one were wholly 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. Two of the 33 were pleased with the care and treatment they received; however, they also made a complaint. One person mentioned the cost of consultations being too high, and the other stated they felt rushed during consultations.

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

- Update the service's prescribing policy to include medication which should not be prescribed.

**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 accompanied by a GP specialist adviser

## Background to London Bioidentical Hormones

London Bioidentical Hormones is an independent service, which provides a range of bespoke healthcare treatments 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 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 is responsible for the management and day to day running of the patient service. In 2020 the service became fully remote.

The service 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.

### **How we inspected this service**

We reviewed a range of information we hold about the service, any notifications received, and the information given by the provider at our request prior to the inspection.

During the inspection we:

- Looked at the systems in place for the running of the service.
- Explored how clinical decisions were made.
- Viewed a sample of key policies and procedures.
- Reviewed feedback from patients about their experiences of 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 Good because:

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

At the inspection in February 2019, we found that this service was not providing safe care in accordance with the relevant regulations because:

- The service was unable to demonstrate they had adequate health and safety arrangements in place to ensure fire safety and the management of legionella.
- The service did not have the full list of emergency medications and did not have a formalised risk assessment outlining why they were not required.
- There was no evidence that fixed electrical installation checks of the premises had been carried out.

The service became fully remote in May 2020. Therefore they no longer need to fulfil the requirements outlined at the last inspection when they saw patients at their clinic.

## Safety systems and processes

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

- The service had appropriate safety policies, which were regularly reviewed.
- They outlined clearly who to go to for further guidance. Staff received safety information from the service as part of their induction and refresher training. The service had systems to safeguard children and vulnerable adults from abuse.
- 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).
- All staff received up-to-date safeguarding and safety training appropriate to their role.
- The service was registered with the Information Commissioner's Office.

## Risks to patients

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

- There were arrangements for planning and monitoring the number of staff needed.
- There was an effective induction system for staff tailored to their role.
- The provider understood their responsibility to manage emergencies and to recognise those in need of urgent medical attention. They knew how to identify and manage patients with severe infections, for example sepsis.
- When there were changes to services or staff the provider 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

### The provider had the information they needed to deliver safe care and treatment to patients.

- Individual patient records were written and managed in a way that kept patients safe. The patient records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.
- The service had systems for sharing information with 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 Department of Health and Social Care (DHSC) guidance in the event that they cease trading.
- Clinicians 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 reliable systems for appropriate and safe handling of medicines.**

- The service provided electronic prescriptions and monitored their use.
- The provider did not prescribe Schedule 2 and 3 controlled drugs (medicines that have the highest level of control due to their risk of misuse and dependence).
- The provider prescribed medicines to patients and gave advice on medicines in line with legal requirements and current national guidance and kept accurate records of medicines. Where there was a different approach taken from national guidance there was a clear rationale for this that protected patient safety.
- The service carried out medicine audits to ensure prescribing was in line with best practice guidelines for safe prescribing.
- There were effective protocols for verifying the identity and age of patients.

## **Track record on safety and incidents**

### **The service had a good safety record.**

- There were comprehensive risk assessments in relation to safety issues.
- The service monitored and reviewed activity. This helped it to understand risks and gave a clear, accurate and current picture that led to safety improvements.

## **Lessons learned and improvements made**

### **The service learned and made improvements when things went wrong.**

- There was a system for recording and acting on significant events. There were no significant events recorded at the service.
- There were adequate systems for reviewing and investigating when things went wrong. For example, we saw that the service received a complaint from a patient who had not received their prescription, which was sent electronically to a pharmacy. The service investigated the complaint and discovered an IT issue with the prescribing system, rectified it and ensured the patient received their prescription.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents.
- The provider kept written records of verbal interactions as well as written correspondence with patients.
- The provider acted on and learned from external safety events as well as patient and medicine safety alerts.

# Are services effective?

**We rated effective as Good because:**

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

**Effective needs assessment, care and treatment**

**The provider had systems to keep clinicians up to date with current evidence based practice.**

**We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service)**

- 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) best practice guidelines.
- Patients' immediate and ongoing needs were fully assessed. Where appropriate this included their clinical needs and their mental and physical wellbeing.
- The provider had enough information to make or confirm a diagnosis.
- We saw no evidence of discrimination when making care and treatment decisions.
- The provider assessed and managed patients' pain where appropriate.
- The provider advised patients what to do if their condition got worse and where to seek further help and support.

**Monitoring care and treatment**

**The service was actively involved in quality improvement activity.**

- The service used information about care and treatment to make improvements. For example, the provider audited the smear data recorded on their system to ensure all patients between 25 and 64 years old had a record of whether cervical screening has been performed. Following the audit, an alert was added to three patient records to prompt the provider to request the information during the next consultation. In addition, a question about smears test results was added to the service's initial patient questionnaire.
- The provider also routinely audited patient consultations to assess the quality of note taking and documentation of licenced and unlicenced medicines.

**Effective staffing**

**The provider ensured staff associated with the service had the skills, knowledge and experience to carry out their roles.**

- All staff were appropriately qualified. The provider had an induction programme for all newly appointed staff.
- Relevant professionals were registered with the General Medical Council (GMC) and were up to date with revalidation.
- The provider understood the learning needs of staff and maintained up to date records of skills, qualifications and training.

**Coordinating patient care and information sharing**

**The provider delivered effective care and treatment.**

- Patients received coordinated and person-centred care. Staff referred to, and communicated effectively with, other services when appropriate. We saw examples of the provider liaising with patients' NHS GP.

# Are services effective?

- Before receiving treatment, patients were required to provide information about their health, any relevant test results and their medicines history. The provider told us that patients would be signposted to more suitable sources of treatment where this information was not available to ensure safe care and treatment.
- 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.
- Patient information was shared appropriately (this included when patients moved to other professional services), and the information needed to plan and deliver care and treatment was available to relevant staff in a timely and accessible way.
- The provider had risk assessed the treatments they offered. The provider told us the medicines prescribed to patients were not liable to abuse or misuse, and were not for the treatment of long term conditions such as asthma. However, this was not documented in their prescribing policy. Where patients agreed to share their information, we saw evidence of letters sent to their registered GP in line with GMC guidance.

## **Supporting patients to live healthier lives**

**The provider was 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, highlighted to patients and where appropriate highlighted to their normal care provider for additional support.
- Where patients needs could not be met by the service, the provider redirected them to the appropriate service for their needs.

## **Consent to care and treatment**

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

- The provider understood the requirements of legislation and guidance when considering consent and decision making.
- The provider supported patients to make decisions and understood the requirement to recorded patient's mental capacity to make a decision, where appropriate.
- The service monitored the process for seeking consent appropriately.

# Are services caring?

**We rated caring as Good because:**

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

## **Kindness, respect and compassion**

**Staff treated patients with kindness, respect and compassion.**

- The service sought feedback on the quality of clinical care patients received.
- Feedback from patients was positive about the way staff treat people.
- The provider understood patients' personal, cultural, social and religious needs and displayed an understanding and non-judgmental attitude to patients.
- The service gave patients timely support and information.

## **Involvement in decisions about care and treatment**

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

- The service was offered on a private, fee-paying basis only and was accessible to people who chose to use it.
- Interpretation services were available for patients who did not have English as a first language. Information leaflets were available on the service's website, to help patients be involved in decisions about their care.
- Patients told us through feedback forms, 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. However, out of 33 patients, one reported feeling rushed during consultations and another complained about the service's consultation fees.
- The provider understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005.

## **Privacy and Dignity**

**The service respected patients' privacy and dignity.**

- The provider recognised the importance of people's dignity and respect.
- Patient records were securely stored.

# Are services responsive to people's needs?

**We rated responsive as Good because:**

**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. It took account of patient needs and preferences.**

- The provider understood the needs of their patients and improved services in response to those needs. For example, patients could email the service and get a response from the provider 24 hours a day if required.
- Appointment times were scheduled to ensure peoples' needs and preferences were met.
- We saw evidence that the service referred patients to other services when appropriate.

## **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.
- Patients with the most urgent needs had their care and treatment prioritised.
- Referrals and transfers to other services were undertaken in a timely way. 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. Staff treated patients who made complaints compassionately.
- The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service had complaint policy and procedures in place. The service learned lessons from individual concerns, complaints and from analysis of trends. It acted as a result to improve the quality of the service. For example, the provider informed us of a complaint of a patient who was finding it difficult to get through to the secretaries via the service's telephone number. As a result, additional provision was put in place so that the secretary service was fully accessible to patients. The service had received two complaints since being in operation; both were dealt with effectively

# Are services well-led?

**We rated well-led as Good because:**

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

## **Leadership capacity and capability**

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

- The provider was knowledgeable about issues and priorities relating to the quality and future of services, and understood the challenges and were addressing them.
- The provider worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.

## **Vision and strategy**

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

- There was a clear vision and set of values. The service had a realistic strategy and supporting business plans to achieve priorities. The provider told us they were considering ways to develop the service as an online business, to provide the best experience for patients.
- The service monitored progress against delivery of the strategy.

## **Culture**

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

- The service focused on the needs of patients.
- The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- The service respected equality and diversity.

## **Governance arrangements**

**There were systems in place to support good governance and management.**

- Structures, processes and systems to support good governance and management were clearly set out, understood and effective. The governance and management of partnerships, joint working arrangements and shared services promoted interactive and co-ordinated person-centred care.
- The provider had established proper policies, procedures and activities to ensure safety and assured themselves that they were operating as intended.

## **Managing risks, issues and performance**

**There were clear and effective processes for 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.
- Performance of clinical staff could be demonstrated through audit of their consultations, prescribing and referral decisions. The provider had oversight of safety alerts and complaints.
- Audit had a positive impact on quality of care and outcomes for patients. There was evidence of action to change the service to improve quality.
- The provider had plans to address major incidents.

# Are services well-led?

## **Appropriate and accurate information**

### **The service acted on appropriate and accurate information.**

- Quality and operational information was used to ensure and improve performance.
- The information used to monitor performance and the delivery of quality care was accurate and useful.
- The service had systems in place to submit data or notifications to external organisations as required.
- 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

## **Engagement with patients, the public, staff and external partners**

- The service involved patients to support high-quality sustainable services.  
The service had a system in place to gather regular feedback from patients. Following each consultation, the service's secretaries send an electronic feedback form to patients.
- The provider told us that weekly meetings were undertaken with the nutritional therapist and secretaries to support advancement of care and support patient outcomes.

## **Continuous improvement and innovation**

### **There was evidence of systems and processes for learning, continuous improvement and innovation.**

- There was a focus on continuous learning and improvement.
- The provider regularly attends conferences, study days and forums to keep up to date with industry practices.
- There were systems to support improvement and innovation work. For example, the provider was working on improving the patient experience by developing a portal for patients to access their own test results.