

# LVL Health

## Inspection report

76 Harley Street  
London  
W1G 7HH  
Tel:  
[www.lvlhealth.co.uk](http://www.lvlhealth.co.uk)

Date of inspection visit: 4 July & 10 August 2023  
Date of publication: 03/10/2023

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.** This is the providers first inspection.

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 this announced comprehensive inspection of LVL Health 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.

LVL Health is a private clinic that provides medical treatment for patients. The main treatment offered are Cannabis-based products for medicinal use (CBPMs), which are prescribed by experienced medical staff working within the latest Governmental guidelines.

The lead nurse 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.

## Our key findings were:

- Care and treatment was delivered according to evidence-based guidelines.
- The provider had systems in place to protect people from avoidable harm and abuse.
- There was a clear vision to provide a safe, personalised, high-quality service.
- Patients could access care and treatment from the service within an appropriate timescale for their needs.
- The service had a comprehensive business development strategy that effectively monitored the service provided to assure safety and patient satisfaction.
- We saw evidence that the provider was engaged with organisations and policy makers in relation to gathering data about the efficacy of CBPMs on non-cancerous chronic pain.

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

# Overall summary

- Review the clinician onboarding induction to make sure it offers a comprehensive training package that would include training around CBPMs, unlicensed medication and internal processes and systems.

**Dr Sean O’Kelly BSc MB ChB MSc DCH FRCA**

Chief Inspector of Healthcare

## Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a specialist adviser and a member of the CQC medicines optimisation team.

## Background to LVL Health

LVL Health is a chronic pain and medical cannabis clinic specialising in treatments for patients who have not found satisfactory results for their conditions with their previous medication. The clinic was set up to carry out a study to evaluate the efficacy and safety of a defined cannabis based medicinal product (CBPM) delivered by inhalation, using a specific device, to patients with chronic non cancer pain. The service is for adults over the age of eighteen. The medicines are prescribed by experienced medical staff working within the latest governmental guidelines.

The service is located at 76 Harley Street, London, W1G 7HH. The building entrance lobby is accessed via steps from the pavement. Wheelchair access is via a ramp at the front of the building. The service has access to consultation rooms and a waiting area for patients. However, at the time of our inspection all consultations took place online.

The usual opening hours are 9am to 5pm Monday to Friday. Patients can also book appointments for evenings and weekends. The medical team comprises of consultants and GPs who specialise in pain. There is a nurse and management and administration staff.

### How we inspected this service

We reviewed information sent to us by the provider remotely prior to attending the inspection. We spoke with the lead nurse, the clinical director and the business director. 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 provided to a third party.

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:**

## **Safety systems and processes**

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

- The landlord for the building conducted safety risk assessments. They had appropriate safety policies, which were regularly reviewed and communicated to staff. 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.
- The service worked with other agencies to support patients and protect them from neglect and abuse. Staff took steps to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable).
- Staff received up-to-date child and adult safeguarding and health and safety training appropriate to their role. All staff were trained to level 3. All staff we spoke with knew how to identify and report concerns.
- The landlord for the building had an effective system to manage infection prevention and control, which had been updated to reflect the changes needed following Covid. The landlords had also carried out Legionella testing.

## **Risks to patients**

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

- There were arrangements for planning and monitoring the number and mix of staff needed.
- At the time of our inspection all consultations were being carried out online. The doctors told us they conducted consultations in private in order to maintain patient confidentiality. All consultants used encrypted and password secure laptops and followed the providers remote consultations protocol.
- Staff understood their responsibilities 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, the consultants told us they would call 999 during a consultation if needed or for acutely unwell patients, they would signpost them to A&E and inform local mental health team and/or GP if concerned.
- There were suitable medicines and equipment to deal with medical emergencies which were stored appropriately and checked regularly. If items recommended in national guidance were not kept, there was an appropriate risk assessment to inform this decision.
- When there were changes to services or staff, the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place. The clinic provided indemnity for all their clinicians.

## **Information to deliver safe care and treatment**

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

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

## Safe and appropriate use of medicines

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

- Clinicians were responsible for keeping their own prescription stationery securely and monitored its use. However, prescriptions were sent directly to the pharmacy and the medicines were delivered by courier to the patient. The patient would have to show identification to receive the medicine and if someone collected it on their behalf they would have to show their own identification and that of the patients.
- The service only prescribed Cannabis-based products for medicinal use (CBPMs) which is a controlled drug (medicines that have the highest level of control due to their risk of misuse and dependence). The service only prescribed one CBPM to patients which could only be used with their device. They gave advice on how to take them in line with legal requirements and current national guidance. Where there was a different approach taken from national guidance there was a clear rationale for this that protected patient safety, which was recorded in the patient's records.
- The medication being used by the clinic, which was a Cannabis based medicine, which are currently 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. Therefore, they must be prescribed and supplied in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance for the prescribing and supply of unlicensed medicines.
- They had effective protocols for verifying the identity of patients before and during a consultation.

## 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. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There were adequate systems for reviewing and investigating when things went wrong. The provider had taken action in relation to the two incidents we reviewed, and we noted this was discussed in their multidisciplinary team (MDT) meetings where all staff attended. All actions and learning were noted.

### When there were unexpected or unintended safety incidents:

- The service gave affected people reasonable support, truthful information and a verbal and written apology.
- They kept written records of verbal interactions as well as written correspondence.
- The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team.

# Are services effective?

**We rated effective as Good because:**

## **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 and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service)**

- CBPMs were legalised in the UK on 1 November 2018, but the regulations around their use and supply remain strict. We noted the provider assessed needs and delivered care in line with relevant and current evidence-based guidance and standards such as National Institute for Health and Care Excellence (NICE) best practice guidelines.
- Patients' immediate and ongoing needs were fully assessed. This included their clinical needs and their mental and physical wellbeing. Clinicians obtained enough information from the patients and their NHS GP to confirm a diagnosis and treatment history prior to carrying out a consultation. Before patients were prescribed a CBPM, the provider would have to be satisfied that they had an 'unmet clinical need' and that patients had tried different treatments for their condition prior to being accepted by the clinic. We saw that the clinic operated a regular MDT, and that all patients had been reviewed before prescribing was started. The appropriate functioning of a MDT is important for clinics prescribing CBPMs, to ensure safe and effective care for patients.
- We saw no evidence of discrimination when making care and treatment decisions.
- One month's supply of medication was prescribed, and patients had to attend follow up consultations to obtain repeat prescriptions. The medication could only be used with the clinic device, which allows a specific dose twice a day.

## **Monitoring care and treatment**

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

- The clinic was initially set up to carry out a study to evaluate the efficacy and safety of a defined CBMP delivered by inhalation to patients with chronic non- cancer pain. The initial trial was for a period of three months and feasibility was assessed through three distinct domains: recruitment and patient experience, medication logistics and data management. Patient experiences were captured using comment forms, requesting feedback on ease of onboarding, ease of answering questionnaires, evidence of questionnaire fatigue and their satisfaction of service. Twelve outcome measures were identified at the beginning of the study, and at the time of our inspection the trial had come to an end. The results were extremely positive in relation to ease of use of the machine and efficiency of CBPM delivery to the patient, tolerability and reduction on severity of pain.
- The service used information about care and treatment to make improvements. The provider carried out monthly quality audits of consultations and clinical record keeping.

## **Effective staffing**

**Staff 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. All consultants were expected to complete an external medicinal cannabis course, attend at least two MDT meetings and shadow consultations prior to carrying out their own consultations. However, we noted that although staff training was up to date at the time of our inspection, not all staff had completed their mandatory training during induction.
- Relevant professionals (medical and nursing) were registered with the General Medical Council (GMC) and Nursing and Midwifery Council and were up to date with revalidation.

# Are services effective?

- The provider understood the learning needs of staff and provided protected time and training to meet them. Up to date records of skills, qualifications and training were maintained. Staff were encouraged and given opportunities to develop.

## Coordinating patient care and information sharing

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

- Patients received coordinated and person-centred care. Staff referred to, and communicated effectively with other services when appropriate. For example, patients could not undertake a consultation until the provider had received confirmation from their GP about their health history and previous treatments.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medicines history. We saw examples of patients being 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. The provider had risk assessed the treatments they offered and they did not prescribe CBPMs if the patient did not give their consent to share information with their GP.
- 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. There were clear and effective arrangements for following up on people who had been referred to other services.

## Supporting patients to live healthier lives

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

- Where appropriate, staff gave people advice so they could self-care. We were told clinicians would have conversations with patients about healthy lifestyles and diet.
- Risk factors were identified, highlighted to patients and where appropriate highlighted to their normal healthcare provider for additional support. Patients and their GPs were made aware of the dangers of not using the CBPMs in the manner prescribed, including the legal consequences.

## Consent to care and treatment

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

- Staff understood the requirements of legislation and guidance when considering consent and decision making.
- Staff 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 for seeking consent appropriately.



# Are services caring?

**We rated caring as Good. because:**

## **Kindness, respect and compassion**

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

- The service sought feedback on the quality of clinical care patients received. Patients were encouraged to leave feedback on various social media platforms. They were also sent feedback questionnaires following their consultations.
- Feedback from patients was positive about the way staff treat people.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients.
- The service gave patients timely support and information.

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

### **Staff 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. Information leaflets were available in easy read formats, to help patients be involved in decisions about their care.
- The patients comments we viewed indicated that they felt listened to and supported by staff and had sufficient time during consultations to make an informed decisions about the treatment available to them.

## **Privacy and Dignity**

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

- Staff recognised the importance of people's dignity and respect. All consultants followed protocols about how a consultation should be conducted when they were not onsite.

# Are services responsive to people's needs?

**We rated responsive as Good because:**

## **Responding to and meeting people's needs**

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

- The provider understood the needs of their patients and improved services in response to those needs. For example, they were collecting data in relation to safety issues and the useability of the inhalation device.
- The facilities and premises were appropriate for the services delivered. However, at the time of our inspection all their consultations were carried out online.

## **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 assessments and consultations.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients reported that the appointment system was easy to use.
- Referrals and transfers to other services were undertaken in a timely way. For example, where the provider had identified mental health concerns, they had made contact with appropriate support services.

## **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 care. For example, they had received a number of complaints about the barcode on the device being too small to scan. They contacted the pharmacy who immediately increased the size of the barcodes supplied.

# Are services well-led?

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

## **Leadership capacity and capability**

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

- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and were addressing them.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.
- The provider had effective processes to develop leadership capacity and skills, including planning for the future leadership of the service.

## **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 service developed its vision, values and strategy jointly with staff and external partners. Their pain clinic aims included researching the best ways to use medical cannabis treatments alongside the patient's primary care treatments, to help manage chronic pain.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.
- The service monitored progress against delivery of the strategy.

## **Culture**

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

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients.
- Leaders and managers acted on behaviour and performance inconsistent with the vision and values.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.
- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing all staff with the development they need. This included appraisal and career development conversations. All staff received regular annual appraisals in the last year. Staff were supported to meet the requirements of professional revalidation where necessary. All staff were considered valued members of the team. They were given protected time for professional development and evaluation of their clinical work.
- There was a strong emphasis on the safety and well-being of all staff.
- The service actively promoted equality and diversity. It identified and addressed the causes of any workforce inequality. Staff had received equality and diversity training. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

## **Governance arrangements**

# Are services well-led?

## **There were clear responsibilities, roles and systems of accountability 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.
- Most staff were clear on their roles and accountabilities; however, we found the clinical lead was not aware of some of the clinics internal processes.
- Leaders 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. For example, there was an alert system set up to notify the provider if the device was malfunctioning which had happened on one occasion. The provider contacted the device manufacturer and the issue was remedied immediately.
- The service had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations. Leaders had oversight of safety alerts, incidents, and complaints.
- Audits 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 provider had plans in place and had trained staff 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.
- Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.
- The service used performance information which was reported and monitored and management and staff were held to account.
- The information used to monitor performance and the delivery of quality care was accurate and useful. There were plans to address any identified weaknesses.
- The service submitted 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 involve patients, the public, staff and external partners to support high-quality sustainable services.**

- The service encouraged and heard views and concerns from the public, patients, staff and external partners and acted on them to shape services and culture.

# Are services well-led?

- Staff could describe to us the systems in place to give feedback. They told us they had weekly meetings where they were invited to give feedback and could also provide feedback anonymously.
- The service was transparent, collaborative and open with stakeholders about performance.

## Continuous improvement and innovation

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

- There was a focus on continuous learning and improvement. The main aim of the clinic was to carry out research into the use of CBPMs in treating chronic pain, with a view to demonstrate it's efficacy to the NHS. The initial research had been approved through the government's clinical trials process and the results were being evaluated at the time of our inspection.
- There were systems to support improvement and innovation work. The dose of CBPMs prescribed was unique to the clinic and could only be taken using a specific device that links with an app. The app provided real time data to the clinic that was used to assess tolerability and effectiveness of this medicine on chronic pain and for a decision to be made in relation to a larger clinical study.
- The service made use of internal and external reviews of incidents and complaints. Learning was shared and used to make improvements.
- Leaders and managers encouraged staff to take time out to review individual and team objectives, processes and performance.